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The Medical Device Safety Act of 2009
S. 540 and H.R. 1346

The Medical Device Safety Act (MDSA) will restore patients' ability to hold medical device manufacturers accountable for injuries caused by defective medical devices. Medical devices include artificial heart valves, implantable defibrillators, catheters, pacemaker wires, and, numerous other medical products.

The bill responds to a 2008 Supreme Court decision, *Riegel v. Medtronic*. That case held that a medical device manufacturer usually cannot be sued by injured patients if the Food and Drug Administration approved the device for marketing through its premarket approval (PMA) process. The Court's decision has restricted consumers' ability to seek compensation from device manufacturers. The Court has given device makers immunity from most product liability claims, and several courts have held that the immunity applies even where defects or other deficiencies become known after approval of the product. This bill has no impact on the authority or ability of the FDA to regulate devices; it merely reinstates the view that FDA regulation and state tort remedies are complementary.

The MDSA restores the complementary nature of the FDA and civil justice system.

FDA regulation and state tort liability each provide a distinct and integral layer of protection for patients. The FDA itself had long recognized that state tort law complements federal regulation. (It was not until 2003 that the FDA suggested that state tort law posed an obstacle to its mission) Tort suits will facilitate the discovery of flaws in devices on the market and, in turn, alert the FDA and the public.

Under the MDSA, manufacturers may continue to use FDA approval as evidence that they acted reasonably in making or labeling their products, but approval will not be a get-out-of-jail-free card that precludes consideration of the facts of a case.

Eliminating state tort suits over medical devices places all responsibility for device regulation in the hands of the FDA, which cannot protect consumers on its own. The FDA's premarket approval process for medical devices does not provide the public with foolproof protection – and was never intended to do so. Even comprehensive pre-market testing cannot uncover all defects or risks posed by a new product. And when a defective device is identified and removed, the agency lacks authority to secure compensation for injured patients. 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."

The MDSA restores fairness and protections for patients.

The MDSA restores a vital and longstanding consumer protection for injured patients: the ability to seek compensation, including medical expenses, pain and suffering, and lost wages, for injuries caused by defective and dangerous medical devices.

Because the federal law provides no avenue for patients to be compensated for their injuries, the MDSA restores their only form of redress: state-law remedies.

The MDSA restores safety incentives, accountability for manufacturers.

As the Supreme Court said in a March 2009 decision, *Wyeth v. Levine*, "manufacturers have superior access to information about their products, especially in the post-marketing phase as new risks emerge."

Injured patients' ability to sue would again provide a greater financial incentive for companies to monitor devices already in the marketplace and provide updated information to the FDA, physicians and other medical professionals.

Restoring accountability under state tort law will deter risky device designs and encourage continued research and testing of devices on the market.

The MDSA restores the same policy for drugs and medical devices.

In March 2009, a year after its *Riegel* decision, the Supreme Court confirmed that drug manufacturers – which are also regulated by the FDA - can be held accountable under state tort law for inadequate warning labels on their products. The MDSA will put medical device manufacturers back on the same footing as drug companies.

The MDSA is the right platform for Congress to clarify its intent.

Senator Edward Kennedy was the sole sponsor of the Senate bill that resulted in the passage of the Medical Device Amendments of 1976 (MDA), legislation aimed at strengthening FDA's authority over medical devices. Kennedy said it was never Congress' intent to give "blanket immunity to manufacturers for injuries caused by faulty devices." Rep. Henry Waxman who was on the House committee that approved the MDA also expressed a similar view – Congress did not intend to bar common law tort actions under the MDA.

The MDSA's key provisions:

The bill amends section 521 of the Federal Food, Drug, and Cosmetic Act and allows injured patients to sue for damages under state law.

The bill is retroactive to the date of enactment of the MDA, reflecting the original intent of the law.