

EDITORIALS



The Medical Device Safety Act of 2009

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Patient safety is a national concern. Major stakeholders throughout our health care system agree that every step must be taken to ensure that medical interventions, used with the intention of improving patients' health, are as safe as possible. But every medical intervention has benefits and risks. Patient safety can be ensured only when the makers of drugs and devices fully and openly disclose both the benefits and the potential adverse effects associated with an intervention. As the Institute of Medicine has made clear, medical devices and drugs need to be assessed for risks and benefits throughout their life cycles.¹

Unfortunately, one major stakeholder, the medical-device industry, has been shielded from the potential consequences of failing to adequately disclose risks. Just over a year ago, the U.S. Supreme Court, in *Riegel v. Medtronic*,² ruled that a medical-device manufacturer cannot be sued under state law by patients alleging harm from a device that received marketing approval from the Food and Drug Administration (FDA). Until that ruling by the Court, the possibility of litigation for "failure to warn" or design defect served as a strong inducement for device companies to be vigilant about the safety of their products.

Since the Supreme Court ruling in *Riegel*, thousands of lawsuits against medical-device manufacturers have been tossed out of court by judges following the Court's lead in deeming such lawsuits to be preempted. We believe that preemption will result in medical devices that are less safe for the American people.

In the largest recent example, Judge Richard Kyle dismissed more than 1000 cases filed against Medtronic in U.S. District Court in Minnesota after the failure of its Sprint Fidelis implantable cardioverter-defibrillator lead, which was with-

drawn from the market in 2007. The lead was prone to fracture, sometimes failed to deliver an appropriate shock, and sometimes delivered multiple unnecessary shocks. Although Kyle stated that "the court recognizes that at least some plaintiffs have suffered injuries from using Sprint Fidelis leads, and the court is not unsympathetic to their plight," he ruled that he was compelled on the basis of the *Riegel* decision to dismiss the suits, leaving injured patients without the possibility of redress.³

And there may be many such patients: more than a quarter of a million Sprint Fidelis leads were implanted worldwide, 150,000 in the United States. The FDA has logged 2200 reports of serious injuries from this lead, and last week Medtronic released an updated mortality report of 13 deaths the company considers to have been related to the Sprint Fidelis.^{4,5}

The Supreme Court's ruling in *Riegel* was based not on considerations of what is best for the health of the public, but rather on a point of statutory law. The Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act provide that a state may not "establish with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable" to a medical device under federal law.⁶ The Court, in an 8-to-1 decision, interpreted this clause as demonstrating Congress's explicit intention to preempt state-law damages suits. The FDA, which until 2003 opposed preemption, in that year inexplicably did an about-face and posited that its approval of a device should be regarded as the final word and should immunize companies against legal liability. With respect to drugs, the FDA announced a broad pro-preemption position in 2006.

In marked contrast to the *Riegel* decision and to the FDA's new position on preemption, a Supreme Court ruling this month in a drug preemption case, *Wyeth v. Levine*,⁷ dismissed Wyeth's argument that failure-to-warn suits against drug companies are preempted by FDA approval of the drug's label. The Food, Drug, and Cosmetic Act contains no explicit preemption clause with regard to prescription drugs. The drug company argued that even though preemption is not specifically mentioned in the Act, it is "implied" by virtue of the supremacy clause of Article IV of the U.S. Constitution, which states that federal law is supreme to state law. In its 6-to-3 ruling, the Supreme Court rejected this argument and found, as well, that the position put forth by the FDA in 2006 "does not merit deference."

As the law now stands, failure-to-warn and design-defect lawsuits are preempted for medical devices but not for drugs. This perplexing state of affairs defies all logic. To address the inconsistency and to improve the safety of medical products, Congressmen Henry Waxman (D-CA), chair of the House Committee on Energy and Commerce, and Frank Pallone (D-NJ), chair of the Health Subcommittee, recently introduced the Medical Device Safety Act.⁸ This bill, along with a companion bill introduced by Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), would nullify the Court's ruling in *Riegel* by adding language to the Medical Device Amendments to make explicit that the law does not preempt suits against device companies, and thereby to place medical devices and drugs on a level playing field with respect to patient lawsuits.

Patients and physicians deserve to be fully informed about the benefits and risks of medical devices, and the companies making the devices should be held accountable if they fail to achieve this standard. We urge Congress to swiftly pass this legislation and to allow lawsuits by injured patients, which have been an important part of the regulatory framework and very effective in keeping medical devices safe, to proceed in the courts. The critical issue of preemption, which directly affects the disclosure of risks and thus the safety of the nation's supply of medical devices and drugs, should properly be decided by officials elected by the people, with whom the responsibility for the health of the public rightfully resides.

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Silent Acid Reflux and Asthma Control

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There are some patients with asthma who have a good response to standard therapy, but there are always some whose symptoms are not well controlled despite treatment with standard asthma medications. Guidelines for the treatment of asthma recommend that patients who have asthma that is difficult to control be evaluated for the presence of coexisting conditions such as gastroesophageal reflux, obesity, obstructive sleep apnea, rhinitis or sinusitis, and chronic stress or depres-

sion, since these conditions could be contributing to the lack of response to therapy. Previously published controlled trials have suggested that treatment with a proton-pump inhibitor alleviates asthma that is associated with symptomatic gastroesophageal reflux.^{1,2} Does this treatment benefit patients with asthma who may have asymptomatic gastroesophageal reflux?

Gastroesophageal reflux is a common syndrome, with 10 to 20% of the population in