



The NEW ENGLAND
JOURNAL of MEDICINE

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BOSTON, MASSACHUSETTS**

HEARING: MEDICAL DEVICE SAFETY ACT OF 2009

**SUBCOMMITTEE ON HEALTH
HOUSE COMMITTEE ON ENERGY AND COMMERCE**

TUESDAY, MAY 12, 2009

Chairman Pallone, Ranking Member Deal, and other distinguished members of the Health Subcommittee, I want to thank you for inviting me to participate in this important hearing. My name is Gregory Curfman, and I am the executive editor of the *New England Journal of Medicine*. I will argue that preemption of common-law tort actions against medical-device companies is ill advised. Preemption puts the interests of corporations before the interests of patients. It denies patients their rights and will result in less safe medical devices for the American people.

For nearly 200 years, the *New England Journal of Medicine* has been publishing articles on new drugs and medical devices. Some have succeeded, but others have failed, in most cases owing to problems with safety. We are a patient-focused medical journal, and much of our work is directed toward ensuring that the potential hazards as well as benefits of medical products are transparently presented in the articles we publish.

Patient Safety: A National Concern

Patient safety is a national concern. But 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 Devices, however, are often approved on the basis of only small clinical trials, and a number of devices have been approved through a fast-track process that does not require any clinical testing at all. The approval process leaves patients vulnerable to safety problems that have gone unrecognized during the premarketing period and emerge only during the postmarketing period.

Preemption and the Medical-Device Industry

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. 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 incentive 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 not only strips patients of their rights but also results in medical devices that are less safe for the American people.

The Case of Sprint Fidelis

In the most 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 withdrawn 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

Tort Litigation and the Public Health

Litigation, or the threat of litigation, has been effective in removing potentially harmful medical products from the market. Examples include the diet pill dexfenfluramine (Redux), the COX-2 inhibitor rofecoxib (Vioxx), and the cholesterol-lowering drug cerivastatin (Baycol). But the examples are not limited to drugs. A number of medical devices have been removed from the market after injuries and litigation, among them the Dalkon Shield, the Bjork-Shiley heart valve, and more recently, as just discussed, the Sprint Fidelis cardioverter-defibrillator lead.

We do not promote lawsuits. We nonetheless oppose preemption, because it removes a legal mechanism by which patients who have been harmed can be

compensated and because it will inevitably result in less safe medical devices for the American people. The way to prevent lawsuits is to put safe medical products on the market.

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.⁴ The Court, in an 8-to-1 decision, interpreted this clause as demonstrating Congress's explicit intention to preempt state-law damage 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 preemption position in 2006.

In marked contrast to the *Riegel* decision and to the FDA's new position on preemption, a Supreme Court ruling last March in a drug preemption case, *Wyeth v. Levine*,⁵ 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 VI of the U.S. Constitution, which states that federal law is supreme over 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."

Preemption: Drugs versus Devices

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. In contrast, in the FDA Amendments Act of 2007,⁶ there is parity between drugs and devices. In establishing a registry for the results of clinical trials, the act made it explicit that the registry applied to clinical trials of not only drugs but also devices.

The Medical Device Safety Act of 2009

To address the legal inconsistency with regard to preemption and to improve the safety of medical products, Congressmen Henry Waxman, chair of the House Committee on Energy and Commerce, and Frank Pallone, chair of the Health Subcommittee, recently introduced the Medical Device Safety Act of 2009.⁷ This bill 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 in the interest of the public health, 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 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.

I hope that this testimony is informative, and I look forward to answering any questions that you may have.

1. Challenges for the FDA: the future of drug safety — workshop summary. Washington, DC: National Academies Press, 2007.
2. *Riegel v. Medtronic*, 552 U.S. 2 (2008).
3. Kyle RH. In re Medtronic, Inc. Sprint Fidelis leads products liability litigation. Multidistrict litigation no. 08-1905 (RHK/JSM). Memorandum opinion and order. U.S. District Court of Minnesota. January 5, 2009. (<http://www.mnd.uscourts.gov/MDL-Fidelis/Orders/2009/090105-08md1905ord.pdf>.)
4. Medical Device Amendments of 1976, codified at 21 U.S.C. §360(k)(a).
5. *Wyeth v. Levine*, 555 U.S. 2 (2009).
6. Food and Drug Administration Amendments Act of 2007, §1102 (codified at 21 U.S.C. §524) (2007).
7. Committee on Energy and Commerce. Health leaders introduce legislation reversing Supreme Court's medical device decision. (http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518.)

