US Court Decision May Be Hazardous to Patients

Public Citizen's *Allison Zieve* examines the implications for patients of the US Supreme Court's decision in *Riegel v Medtronic.*

For 32 years, the US Food and Drug Administration has regulated the entry of medical devices onto the market. Throughout that time, US consumers injured by medical devices have been able to bring, and often to win, product liability lawsuits seeking compensation from device manufacturers for injuries caused by medical devices. Last month, the Supreme Court held that the law that provides authority for the FDA to regulate devices also severely limits the right of injured patients to sue device manufacturers[1]. The decision creates a hazardous hole in the US system for protecting public health.

Pre-emption

The Supreme Court relied on a legal doctrine known as pre-emption, which is based on the idea that when state and federal law conflict, state law must give way. However, product liability suits – which are based on state law – are not inconsistent with federal regulation. A verdict for a plaintiff does not require a device manufacturer to take any action inconsistent with FDA regulation; it requires only that the company pay money to the injured patient.

Product liability suits provide an important complement to federal regulation. As former FDA chief counsel Margaret Porter has explained[2]: "Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Pre-emption of all such claims would result in the loss of a significant layer of consumer protection."

Losing this layer of protection is particularly worrisome at this time. Recent reports from the FDA itself, from the National Academy of Sciences' Institute of Medicine, and from the Government Accountability Office have documented the FDA's inability to protect the public from dangerous medical devices and pharmaceuticals[3-6]. Noting some of the same concerns discussed in the reports, another former FDA chief counsel, Peter Barton Hutt, testified before Congress in January[7] that science at the FDA today "is in a precarious position". "In terms of both personnel and the money to support them," Mr Barton Hutt said, "the agency is barely hanging on by its fingertips".

The debate over whether federal regulation immunises device manufacturers from lawsuits seeking damages caused by devices is not just an abstract argument over legal doctrine.

Rather, the court's recent decision threatens the safety of current and future devices. The possibility of being held liable for injuries caused by their products creates an invaluable incentive to companies to make sure that their products are as safe and effective as they can be before they bring them to market, to revise labels to warn of newly discovered hazards and to remove devices from the market when experience shows that they pose too great a risk to patients. Lawsuits also provide the sole means for patients injured by harmful devices to seek compensation.

Benefits of litigation

Lawsuits by injured patients can have other salutary effects as well.

For example, a lawsuit over the defective Shiley heart valve led to the creation of a fund that not only provided compensation to patients, but also paid for research to try to identify which of the valves still implanted in patients' chests were most likely to fracture, to help determine whether explant surgeries were worth the risk. Lawsuits involving certain bone screws brought to light information about the safety of these devices that the FDA had not seen before. Individual suits over injuries caused by the pain reliever Vioxx (rofecoxib) helped to change public perception and medical journal practices about the publication of industry-funded studies.

In recent years, device manufacturers have recalled a number of FDA-approved devices from the market for safety reasons (for example, several Medtronic implantable defibrillators, St Jude Medical's Silzone heart valves, Sulzer hip and knee prostheses and Guidant implantable defibrillators). And the agency has been slower than the UK or Canada, for instance, to strengthen warnings on drug labels (selective serotonin re-uptake inhibitors, for example) and to remove unsafe products from the market (troglitazone and nefazodone, for example).

In these circumstances, the role of lawsuits as an incentive for companies not to prioritise profit over safety and as a remedy for consumers is especially crucial.

References

1. *Riegel v Medtronic, Inc,* US Supreme Court No 06-179, 20 February 2008, www.supremecourtus.gov/opinions/07pdf/06-179.pdf
2. Porter M, The Lohr Decision: FDA Perspective and Position, *Food & Drug Law Journal*, 1997, **52**, 7-12
3. FDA Science and Mission at Risk; Report of the Subcommittee on Science and Technology, 20 November 2007, www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf
4. Struggling with Science: A Critical Look at the US FDA, *The Regulatory Affairs Journal – Devices*, 2008, **16**(1), 9-12
5. The Future of Drug Safety: Promoting and Protecting the Health of the Public, Institute of Medicine, 22 September 2006, www.nap.edu/catalog.php?record_id=11750
6. Improvement Needed in FDA's Postmarket Decision-making and Oversight Process, Highlights, GAO-06-402, GAO, March 2006, www.gao.gov/new.items/d06402.pdf
7. Peter Barton Hutt testimony, 29 January 2008, http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.012908.FDASelfAssessment.shtml

Allison Zieve is a lawyer at Public Citizen, a consumer advocacy organisation based in Washington, DC. She represented the patient in the recent US Supreme Court case *Riegel v Medtronic, Inc.*