



Center for Justice & Democracy
90 Broad Street, Suite 401
New York, NY 10004
Tel: 212.267.2801
centerjd@centerjd.org
<http://centerjd.org>

THE WYETH CASE, CORPORATE IMMUNITY AND “PREEMPTION”

The Bush Administration has recently stepped up efforts, through federal agencies, to “preempt” or take away, the legal rights of Americans injured by defective or dangerous products. The goal is complete immunity for corporations that are negligent or deliberately irresponsible and cause injury or death.

- The Administration argues that someone injured by a product that complies with a federal agency’s regulation, including unsafe drugs, medical devices and cars, should not be allowed to sue and obtain compensation from the culpable manufacturer.
- The mechanisms used by the Administration to accomplish this agenda are primarily agency rules, regulations and arguments in court cases.
- Congress never intended federal agencies to have this kind of power and to overturn fundamental legal rights; this movement by the Bush Administration is unprecedented in history.

The U.S. Supreme Court has already started to move toward affirming the Administration’s agenda.

- In *Riegel v. Medtronic* (Feb. 2008), the Court said that a company producing certain Food and Drug Administration (FDA)-approved medical devices is completely immune for causing deaths and injuries.ⁱ
- Senator Ted Kennedy (D-Mass.), Chairman of the Senate Committee on Health, Education Labor and Pensions, responded that “[i]n enacting legislation on medical devices, Congress never intended that F.D.A. approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices.”ⁱⁱ
- Legislation has now been introduced in Congress to reverse the *Riegel* decision.ⁱⁱⁱ

In November 2008, the Supreme Court will consider a much broader case, *Wyeth v. Levine*, which will decide the same issue with regard to prescription and over-the-counter drugs, and perhaps even more products.

- The *Wyeth* case was brought by Diana Levine, a professional guitarist whose right arm was amputated after an anti-nausea drug was improperly injected into an artery.^{iv} Though the manufacturer, *Wyeth*, knew injection could cause gangrene, there was no explicit warning on the label.

- A Vermont jury awarded Levine \$6.7 million; the verdict was upheld by the state Supreme Court. The U.S. Supreme Court will now decide whether to reverse these decisions and give the pharmaceutical company complete immunity.
- Among those who reject the Bush Administration's position and believe that federal agencies are unable to ensure safety, that regulated products still present risks and that companies will cut corners if given immunity, are the editors of the *New England Journal of Medicine*,^v forty-seven state attorneys general and former FDA commissioners David Kessler and Donald Kennedy.^{vi}

If the U.S. Supreme Court upholds the concept of corporate immunity (“preemption”) in the *Wyeth* case, so that a person may not sue if they are injured by a drug that meets federal safety regulations, many believe:

- Corporate responsibility for ensuring product safety will be undermined, especially the continuing responsibility of a company to learn and disclose new things about a product's safety;
- It will be impossible for those legitimately injured by an unsafe drug manufactured by a negligent or deliberately irresponsible corporation to obtain compensation.

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NOTES

ⁱ *Riegel v. Medtronic*, 128 S.Ct. 999 (2008).

ⁱⁱ Linda Greenhouse, “Justices Shield Medical Devices From Lawsuits,” *New York Times*, February 21, 2008, found at <http://www.nytimes.com/2008/02/21/washington/21device.html>.

ⁱⁱⁱ Dave Lenckus, “Drugmaker product liability shields set for legal tests,” *Business Insurance*, September 15, 2008, found at <http://www.businessinsurance.com/cgi-bin/article.pl?articleId=25872>; Press release from the Office of Senator Edward Kennedy, “Kennedy, Colleagues Introduce Bill To Reverse Supreme Court Decision, Protect Consumers From Dangerous Medical Devices,” July 31, 2008, found at http://kennedy.senate.gov/newsroom/press_release.cfm?id=9E5214E5-F445-49F5-BE9A-132B304980A2.

^{iv} David G. Savage, “Drug makers seek shield from lawsuits,” *Los Angeles Times*, September 7, 2008, found at <http://www.latimes.com/news/nationworld/washingtondc/la-na-scotus7-2008sep07,0,3541470,full.story>; Alicia Mundy, “Plaintiffs’ Lawyers Fight Restrictions On Product-Liability Suits,” August 13, 2008, found at <http://online.wsj.com/article/SB121858968255135401.html>; *Wyeth v. Levine*, *On The Docket*, found at <http://otd.oyez.org/cases/2008/wyeth-v-levine> (site visited October 22, 2008); *Wyeth v. Levine*, No. 06-1249, *cert. granted* 128 S.Ct. 1118 (January 18, 2008).

^v Ricardo Alonso-Zaldivar, “Lawsuits help guarantee drug safety, doctors say,” *Associated Press*, August 15, 2008, found at <http://www.wtopnews.com/?nid=343&sid=1460815>.

^{vi} *Ibid.*