



Why Doctors Should Worry about Preemption

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A leading drug company may be poised to win a landmark legal victory next fall. If the drug manufacturer, Wyeth, prevails in a case soon to be argued before the U.S. Supreme Court (*Wyeth v. Levine*),¹

drug companies could effectively be immunized against state-level tort litigation if their products that have been approved by the Food and Drug Administration (FDA) are later found to be defective.

A medical-device company won such a victory in April. In *Riegel v. Medtronic*,² the Supreme Court determined that a product-liability lawsuit against Medtronic in a state court was preempted because the device had received FDA approval. Preemption is a legal doctrine based on the supremacy clause of the U.S. Constitution, which states that when federal and state laws are at odds, federal law takes precedence. Its application to state tort litigation is a radical extension of its original meaning.

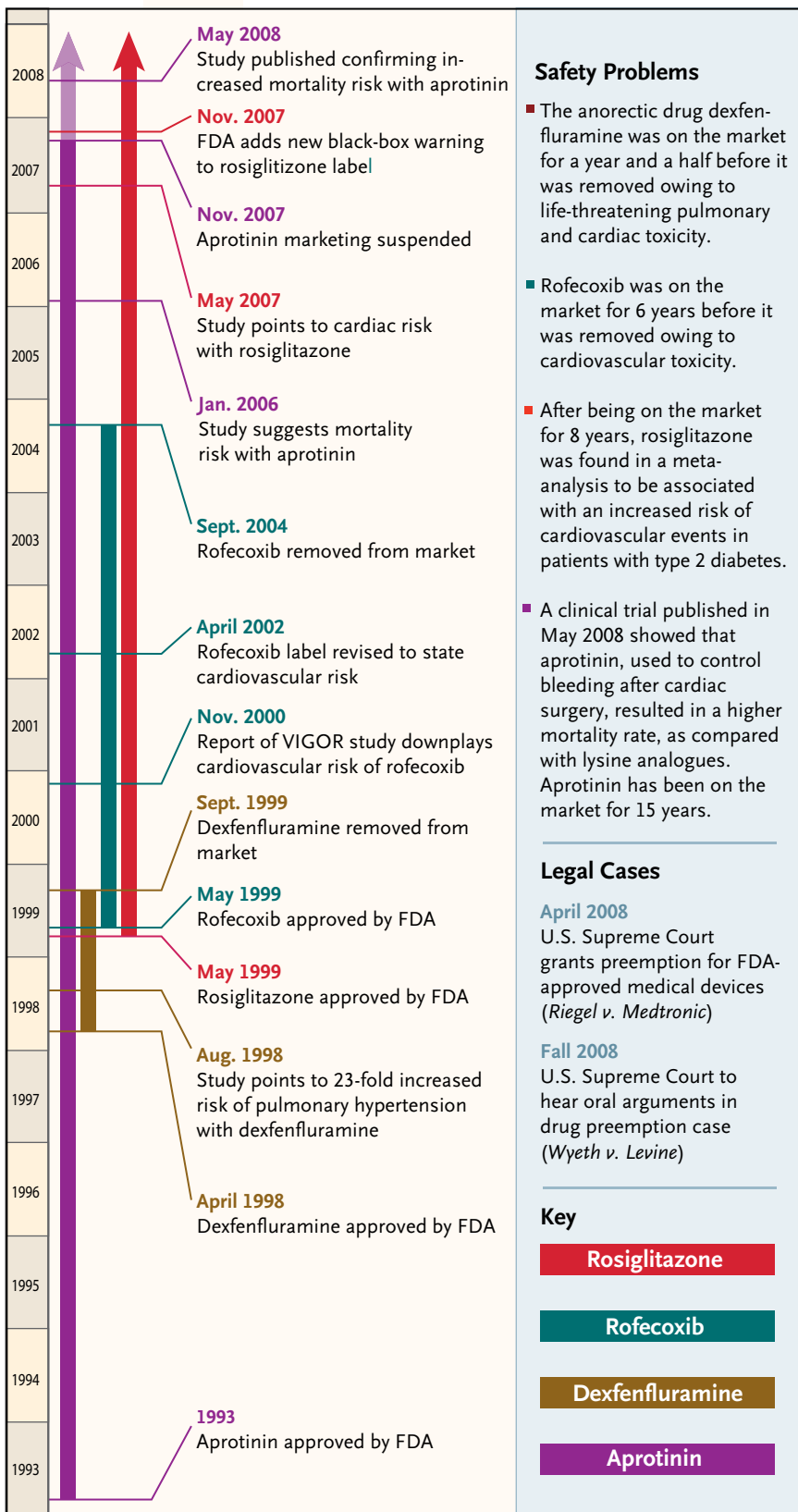
Medtronic won its case because the 1976 law that grants the FDA authority to regulate medical de-

vices contains a clause asserting that state requirements with regard to medical devices are preempted by federal requirements. Although the preemption clause is silent on common-law tort actions, the Supreme Court (with Justice Antonin Scalia writing for the Court) interpreted the preemption clause broadly to include such actions.

Unlike the law governing medical devices, the Food, Drug, and Cosmetic Act, which provides the statutory framework for the regulation of drugs by the FDA, contains no such preemption clause. Thus, in *Wyeth v. Levine* — which concerns a patient who lost her arm after an injection of Wyeth's antiemetic drug Phenergan — the Court will decide whether preemption of state tort litigation is implied by the law, even though it is not explicitly stated.

Previous administrations and the FDA considered tort litigation to be an important part of an overall regulatory framework for drugs and devices; product-liability litigation by consumers was believed to complement the FDA's regulatory actions and enhance patient safety. Margaret Jane Porter, former chief counsel of the FDA, wrote, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."³ Persons who are harmed have the right to seek legal redress. Preemption would erase that right.

But in the past few years, the government's views have shifted, and the FDA has reversed its position, now claiming that common-law tort actions are preempted. The FDA argues that tort liability stifles innovation in product development and delays the approval process, and that lay juries are incapable of making determinations about product safety. It has been argued, however, that Con-



Four Drugs with Safety Problems Discovered after FDA Approval.

Safety Problems

- The anorectic drug dexfenfluramine was on the market for a year and a half before it was removed owing to life-threatening pulmonary and cardiac toxicity.
- Rofecoxib was on the market for 6 years before it was removed owing to cardiovascular toxicity.
- After being on the market for 8 years, rosiglitazone was found in a meta-analysis to be associated with an increased risk of cardiovascular events in patients with type 2 diabetes.
- A clinical trial published in May 2008 showed that aprotinin, used to control bleeding after cardiac surgery, resulted in a higher mortality rate, as compared with lysine analogues. Aprotinin has been on the market for 15 years.

Legal Cases

- April 2008**
U.S. Supreme Court grants preemption for FDA-approved medical devices (*Riegel v. Medtronic*)
- Fall 2008**
U.S. Supreme Court to hear oral arguments in drug preemption case (*Wyeth v. Levine*)

Key

- Rosiglitazone
- Rofecoxib
- Dexfenfluramine
- Aprotinin

gress, not unelected appointees of a federal agency, has the power to decide whether preemption should apply.

Drug and device companies have chosen an inauspicious moment to attack the right of patients to seek redress. A series of pivotal reports on patient safety from the Institute of Medicine, as well as numerous articles in scholarly journals, has put the issue of patient safety in the national spotlight. Although frivolous lawsuits should not be condoned, product-liability litigation has unquestionably helped to remove unsafe products from the market and to prevent others from entering it. Through the process of legal discovery, litigation may also uncover information about drug toxicity that would otherwise not be known. Preemption will thus result in drugs and devices that are less safe and will thereby undermine a national effort to improve patient safety.

Owing in part to a lack of resources, approval of a new drug by the FDA is not a guarantee of its safety (see timeline).⁴ As the Institute of Medicine has reported, FDA approval is usually based on short-term efficacy studies, not long-term safety studies.⁵ Despite the diligent attention of the FDA, serious safety issues often come to light only after a drug has entered the market. The FDA, which — unlike most other federal agencies — has no subpoena power, knows only what manufacturers reveal.

Why should doctors be concerned about preemption? In stripping patients of their right to seek redress through due process of law, preemption of common-law tort actions is not only unjust but will also result in the reduced safety of drugs and medical de-

vices for the American people. Preemption will undermine the confidence that doctors and patients have in the safety of drugs and devices. If injured patients are unable to seek legal redress from manufacturers of defective products, they may instead turn elsewhere.

In May, a Congressional hearing on preemption was held by Representative Henry Waxman (D-CA) and the House Committee on Oversight and Government Reform. As we stated in our testimony to the committee, to ensure the safety of medical devices, we

urge Congress to act quickly to reverse the *Riegel* decision. Congressman Waxman and Congressman Frank Pallone, Jr. (D-NJ), are poised to introduce legislation that would unambiguously eliminate the possibility of preemption of common-law tort actions for medical devices. And if the Supreme Court rules for preemption in *Wyeth v. Levine*, which we hope it will not, Congress should consider similar legislation for drugs. Such legislation is in the best interest of the health and safety of the American public.

Dr. Curfman is the executive editor, Dr. Morrissey the managing editor, and Dr. Drazen the editor-in-chief of the *Journal*.

1. *Wyeth v. Levine*, cert. granted, 128 S. Ct. 1118 (2008).
2. *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).
3. Porter MJ. The *Lohr* decision: FDA perspective and position. *Food Drug Law J* 1997; 52:7-11.
4. Kessler DA, Vladeck DC. A critical examination of the FDA's efforts to preempt failure-to-warn claims. *Georgetown Law J* 2008; 96(2). (Accessed June 13, 2008, at <http://lsr.nellco.org/georgetown/ois/papers/2/>.)
5. Baciou A, Stratton K, Burke SP, eds. *The future of drug safety: promoting and protecting the health of the public*. Washington, DC: National Academies Press, 2007.

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Collective Accountability for Medical Care — Toward Bundled Medicare Payments

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Medicare's projected spending growth is unsustainable. The program already strains the resources of beneficiaries and taxpayers alike and will someday crowd out other public- and private-sector priorities, given that Medicare spending as a percentage of the gross domestic product is expected to nearly double in the next 20 years. At the same time, neither beneficiaries nor taxpayers are getting good value from the program. Per-beneficiary spending in high-spending regions of the country exceeds that in low-spending regions by one third, and yet beneficiaries in high-spending regions receive no better quality of care.¹ The incentives inherent in the dominant fee-for-service payment system are the root cause of these problems. Fee-for-service payment spurs spending growth, supports a fragmented and compartmentalized delivery system, and does nothing to reward quality or value.

In our June 2008 report, the Medicare Payment Advisory Commission (MedPAC) makes three recommendations intended to create collective accountability across providers for selected hospital episodes, such as those for congestive heart failure, chronic obstructive pulmonary disease, and cardiac bypass surgery. Our hope is that this set of policies will create an environment that encourages and enables providers to accept bundled payments while also testing the feasibility of this payment design. Under a bundled payment approach, Medicare would pay a single provider entity (comprising a hospital and its affiliated physicians) a fixed amount intended to cover the costs of providing the full range of Medicare-covered services delivered during the episode, which might be defined as the hospital stay plus 30 days after discharge. Bundling payments in this way should provide incentives to increase efficiency, coordinate

in-hospital and post-hospital care, and, if combined with pay-for-performance initiatives, improve the quality of care.

Standardized Medicare spending for an episode of care varies greatly among hospitals (see table). The greatest variation occurs in spending for readmission and post-acute care. Variation in spending for physicians' services after discharge (included in the "other" category) is also notable. Physicians influence the variation in the use of both their own services and all other services. They also influence hospitals' costs, since they exercise their judgment in determining the length of a patient's stay and the use of the intensive care unit and surgical supplies, for example. Accordingly, to encourage joint accountability for both the volume and the cost of services, payment for physician services as well as hospital and other post-acute care services must be included in the bundle.