



“Implied” preemption: The United States Supreme Court and the New England Journal of Medicine

The Roberts Court puts the legal battle over preemption front and center

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The concept of “implied preemption” rests on a counter-intuitive basis. Essentially, the theory is that when Democratic congresses enacted legislation to police egregious conduct by product manufacturers, they meant to immunize these same manufacturers from the consequences of state court product liability lawsuits. Nevertheless, preemption in this context has at times been “implied” by courts, even though the subject statutes never mentioned state court product liability lawsuits at all. The belief that such “implied” preemption was intended by the framers of these statutes is counter-intuitive, because it is utterly inconsistent with the politics of these enacting legislatures to have “implied” that victims of egregious conduct would be left out in the cold with no remedy.

Until the 1990s, companies rarely moved for summary judgment on the basis of supposed preemption. Most preemption litigation involved toxic torts and the labeling requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) – matters that the Supreme Court dealt with in 2005 in the case of *Bates v. Dow AgroSciences LLC* (2005) 544 U.S. 431. Because it was widely recognized that state law was

complementary to Food and Drug Administration (FDA) action, the defense’s efforts in pharmaceutical litigation through much of the 1990s went towards lobbying for strengthened requirements before necessary experts could testify. For example, the seminal case of *Daubert v. Merrell Dow Pharmaceuticals* (1993) 509 U.S. 579 was about the drug Bendectin.

Moreover, until a policy change by the administration of George W. Bush, the FDA itself generally viewed state law failure-to-warn claims as complementing federal regulatory efforts by bringing to light drug risks unknown or underappreciated. (See the article by former FDA chief counsel Margaret Porter, *The Lohr Decision: FDA Perspective and Position*, Food and Drug Law Journal, 1997; 52:7-11.) However, the Bush administration radically altered the preemption debate. From the FDA to National Highway Traffic Safety Administration (NHTSA), it has promoted the concept of preemption, particularly in preambles to new regulations. In fact, the FDA’s counsel even appeared at defense conferences and provided previously unheard of amicus support for preemption briefing. Summary judgment motions based upon preemption have mushroomed.

In this environment, the Roberts Court has placed preemption front and center. Just this past year, in *Riegel v. Medtronic* (2008) 128 S. Ct. 999 (though

decided on the basis of “express” preemption), manufacturers of defective medical devices succeeded in convincing the Court to immunize them from almost any liability for the often-horrific injuries caused by their dangerous products. While on March 3, 2008, the Court affirmed a ruling that a drug manufacturer that had failed to warn the public about the dangers of its product – and may have hidden key information from the federal government regarding the risks of its drug – could not hide behind a Michigan statute that provided immunity to prescription drug manufacturers. The case was decided on a 4-4 vote with Roberts recusing himself. (*Warner-Lambert, LLC v. Kent* (2008) 128 S. Ct. 1168.)

Last Spring, on the very last day that the Supreme Court selected cases, to the surprise of all, the Supreme Court accepted certiorari in two cases involving critical issues of preemption. In *Altria vs. Good*, No. 07-562 (U.S. cert. granted Jan. 19, 2008), the court agreed to review the First Circuit’s decision that the Federal Cigarette Labeling Act did not preempt suits related to the fraud of “light” cigarettes.¹ On the very same day, the Court also agreed to review the decision of the Vermont Supreme Court that a case brought against Wyeth for its prescription drug Phenergan should not be preempted. The U.S. Supreme Court will hear oral arguments in *Altria vs. Good* on



October 6 and in *Wyeth v. Levine*. (*Wyeth v. Levine*, cert. granted, 128 S. Ct. 1118 (2008) on November 3, 2008.

Wyeth v. Levine

The plaintiffs in *Wyeth v. Levine* alleged that Wyeth's label for its drug Phenergan should have warned against a method of administering the drug directly into a vein (called "IV push"). In April 2000, Diane Levine, a guitar player, was treated for nausea associated with migraine headaches. Levine was given two injections of Phenergan, the second of which was administered using the dangerous "IV push" method. When the Phenergan was errantly injected into her artery, it caused necrosis in her hand and arm. This was followed by gangrene that required the later amputation of her forearm. A Vermont state court jury awarded her \$6.7 million.

Wyeth, the manufacturer of Phenergan, then appealed, arguing that the jury's finding operated to regulate Phenergan in a way that conflicted with the FDA. The Vermont Supreme Court, however, held that there was no conflict between Wyeth's duty to warn under Vermont common law and the warning label for Phenergan approved by the FDA. In reaching its decision, the Court noted that a great majority of courts addressing the issue had rejected drug companies' preemption arguments in similar circumstances. The Court concluded that FDA-approved warnings "create a floor, not a ceiling, for state regulation," basing its decision in part on the savings clause in the Food, Drug, and Cosmetics Act which allows manufacturers to avoid state failure-to-warn claims without violating federal law through unilateral changes to their drug labels when these become necessary to make their products safer.

Why Wyeth v. Levine is important to everyone

Given its potential impact on the fate of pharmaceutical litigation, the national attention given to the case of *Wyeth*

v. Levine is more than justified. Potentially, the Supreme Court could find that all lawsuits against pharmaceutical companies based upon their failure-to-warn of adverse risks are barred.

This would strike a major blow to pharmaceutical litigation, because the vast majority of the litigation is based upon the legal theory that drug manufacturers have failed to warn of specific adverse consequences when they should have. In response to this grave threat, 21 separate amicus curiae briefs were filed with the Supreme Court requesting that the Vermont Supreme Court's decision in favor of Levine be affirmed. Indeed, every state attorney general other than the Attorneys General of Michigan, Nebraska and Texas, supported the State of Vermont, as did two former FDA commissioners (David Kessler, who served in the Clinton Administration, and Donald Kennedy who served in the Administration of George H. W. Bush.) Predictably, though, the Solicitor General entered the fray on Wyeth's side.

The New England Journal of Medicine joins forces with plaintiffs' lawyers

Lawyers were not alone in recognizing the adverse impact that giving practical immunity to pharmaceutical companies could have on the American healthcare delivery system. The editors of the prestigious New England Journal of Medicine (NEJM) also concluded that the tort system was an essential component in preventing pharmaceutical companies from acting in ways that adversely affected the healthcare system. In an editorial on July 3, 2008, Editors Curfman, Draven and Morrisey wrote about the potentially severe consequences of a decision in favor of preemption. (*See, Why Doctors Should Worry About Preemption*, NEJM 359:1-3.) In their editorial, the editors cautioned that "preemption will . . . result in drugs and devices that are less safe and will thereby undermine a national effort to improve patient safety."

(*Ibid.*) They also opined that the beneficial deterrent function of the tort system is essential: ". . . immunity undermines the tort system's goal of deterring unreasonably dangerous actions or omissions." (*See, Curfman, Draven and Morrisey, A Pivotal Medical Device Case*, NEJM, 358:76-77.)

The editors of the New England Journal of Medicine and Public Justice

Subsequent to their editorials, the NEJM editors requested one of the authors of this article to prepare an amicus curiae brief for the U.S. Supreme Court in support of the State of Vermont.ⁱⁱ In all, 10 current and former editors and contributing authors of the NEJM, including every editor-in-chief since 1977, appeared as amici on the brief of the "New England Journal of Medicine Editors and Authors." This was extraordinary, as it was the first time that the NEJM or its editors had ever appeared on a Supreme Court brief in support of a party. As a Wall Street Journal article highlighting the brief noted, the medical editors and writers "plunged into an escalating legal battle" with enormous national implications.

Also contributing to the final brief were Public Justice attorneys, Arthur Bryant and Leslie Brueckner. Significantly, Arthur Bryant had argued the case of *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861 before the U.S. Supreme Court and Leslie Brueckner had argued before the U.S. Supreme Court in the preemption case of *Spiritsma v. Mercury Marine* (2002) 537 U.S. 51.

What the brief asserts

In their brief, the NEJM editors and authors urged the Court to reject Wyeth's attempt to immunize itself from liability for inadequately labeled drugs because FDA labeling requirements have proven to be insufficient to protect consumers from dangerous side effects of prescrip-



tion drugs. The editors and authors explained that the FDA cannot ensure the adequacy of prescription drug labels.

Relying on studies conducted by the government, the brief illustrated the structural limitations the FDA is faced with in the drug approval and labeling process. First, the FDA is limited to the information that is submitted by the drug manufacturers themselves. As stated by NEJM editor-in-chief, Dr. Jeffrey Drazen, in an Associated Press interview, “. . . even if the FDA is doing the best it can, it simply can’t see the future clearly enough to pre-empt manufacturers from litigation.” (See, *Lawsuits Help Guarantee Drug Safety, Doctors Say*, San Francisco Examiner, August 15, 2008.) Further, when new risks become known after a drug’s label has been approved, the FDA has only limited authority to force a manufacturer to change its label to reflect the newly discovered risks, whereas the drug companies have unilateral power to change their labels. As a result, drugs with inadequate labels are left on the market long after the drug companies become aware of the drug’s dangerous side effects and thousands of consumers’ lives have been ruined.

The NEJM brief includes numerous examples of drugs that were approved by the FDA as safe but later withdrawn from the market because of serious side effects. (See, Appendix “A” to the brief, which can be downloaded in PDF format from www.publicjustice.net/briefs_documents.htm.) In particular, the histories of Pondimin/Redux, Vioxx and Trasyolol are examined in great detail, illustrating the grave danger of accepting Wyeth’s argument of “implied” preemption. Reading just these three examples clearly demon-

strates the grim reality: that on a number of critical occasions, prescription drug manufacturers have withheld their knowledge from the FDA about a drug’s dangerous side effects during the approval process and then later lobbied against stricter post-approval warning labels. While doing so, they have aggressively marketed their products, earning hundreds of millions to billions of dollars even after their products injured or killed thousands of consumers.

Consumers benefit from lawsuits against drug manufacturers

Finally, the editors and authors point out that litigation-induced discovery is often the only way to dig up information regarding the inadequacy of drug labels and the side effects that the drug companies never disclosed to the FDA, doctors, or the public.

This “feedback loop” of discovery conducted as a result of litigation provides the FDA with the information it needs to pressure drug manufacturers to improve their labels. Litigation also serves as the vehicle by which victims can improve their lives after receiving compensation from the drug manufacturers for their injuries. As Dr. Drazen noted, “. . . the (court) system represents one of the key defense mechanisms that individuals have if a manufacturer has not made the risks of a product clear to the public.” (*Ibid.*)

Conclusion

If the Supreme Court accepts Wyeth’s position, the decision would radically change the traditional state law remedial process that has developed over the past century. The courthouse doors

would be closed to thousands of future prescription drug users who will suffer severe injuries. The NEJM editors and authors fear the ramifications of this decision upon the American healthcare delivery system. As their brief points out, “. . . it is chilling to imagine how [drug] companies might conduct themselves if the threat of tort liability for dangerous drugs were eliminated completely” by

preemption . . . Preemption of failure to warn claims would substantially threaten” the public health.

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Endnotes:

ⁱ Gerson H. Smoger is counsel of record in the case of *Altria v. Good* for amici the American Medical Association, the American Cancer Society, Inc., the Campaign for Tobacco-Free Kids, the American Heart Association, the American Lung Association, the American Public Health Association, the American Legacy Foundation, the American College of Chest Physicians, the Oncology Nursing Society and the American Academy of Pediatrics.

ⁱⁱ Gerson H. Smoger is counsel of record for amici curiae, the New England Journal of Medicine Editors and Authors. The brief is available at http://www.publicjustice.net/briefs_documents.htm. Public Justice contributed to the brief as part of its Federal Preemption Project, a nationwide campaign dedicated to preserving injured consumers’ access to justice. Public Justice has advocated against preemption for years.