

The Legal Intelligencer

THE OLDEST LAW JOURNAL IN THE UNITED STATES 1843-2009

PHILADELPHIA, APRIL 8, 2009

An **ALM** Publication

Wyeth v. Levine: A Monumental Victory for Consumers

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In a 6-3 decision March 4, the U.S. Supreme Court ruled in *Wyeth v. Levine* that, in the absence of express congressional intent, drug manufacturers could not use the federal pre-emption defense to escape liability for harm caused by their products. This decision had been long anticipated by both the plaintiff and defense bar. In soundly rejecting the pre-emption defense, the Supreme Court examined the Supremacy Clause of the U.S. Constitution, the dual system of sovereignty between the states and the federal government (federalism), the applicability of the 10th Amendment and, most notably, the importance of regulatory findings on pre-emption.

This decision is a victory not only for citizens harmed by dangerous prescription drugs, like Diana Levine, but for all citizens who seek justice in state court actions against powerful corporations. The decision also restores the balance of regulation by no longer allowing manufacturers to hide behind “statements” by executive agencies that are often poorly funded, under-staffed and sometimes subject to political influence.

THE SUPREMACY CLAUSE AND THE 10TH AMENDMENT

Pre-emption is a doctrine that bars a citizen’s right to make a claim in state court under state laws. Under the Supremacy Clause of the U.S. Constitution, the laws of the United States are “the supreme law of the land ... anything in the Constitution or laws of any State to the contrary notwithstanding.” This powerful language invalidates all state laws that conflict or interfere with an act of Congress. Congress can either expressly pre-empt an area of law in the statute itself or pre-emption can be implied from Congress’ intent. Where Congress has not expressly declared its intentions, courts have traditionally looked to the purposes and

intentions behind enabling legislation and regulatory actions to determine if state law is pre-empted.

The drafters of the Constitution were well aware of the inherent risk in restricting the sole exercise of police powers to one centralized government. Thus, “to ensure the protection of our fundamental liberties,” the Constitution established a system of dual sovereignty between the states and the federal government. The Constitution’s 10th Amendment states that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people.” Preservation of states’ police powers was discussed specifically in “The Federalist Papers.” (See *Texas v. White Wall* .) The 10th Amendment’s creation of a dual civil justice system requires a strict, narrow reading of the Supremacy Clause. However, there have been several Supreme Court decisions where state common law was pre-empted based upon “deference” given to certain regulatory action, even in the absence of any statutory language. (See, e.g., *Geier v. American Honda* .)

This tension between the Supremacy Clause and the 10th Amendment created uncertainty in the courts, which were faced with an increasing number of motions asserting implied pre-emption as a bar to consumer litigation.

PRE-EMPTION AND CONSUMER LITIGATION BEFORE WYETH

Cigarette manufacturers, and later drug companies, brought creative pre-emption arguments in a growing number of state courts (less successfully) and various federal courts of appeals (more successfully). Aside from the legal issues, numerous practical questions were raised by these decisions: Were regulatory agencies able to protect our safety? Would common law litigation still perform a useful role in keeping Americans safe?

Our Supreme Court considered these questions unsettled, so, in its 2007-2008 and 2008-2009 sessions, it granted certiorari petitions in six cases involving pre-emption and held in abeyance, pending those opinions, at least two additional cases from the 3rd U.S. Circuit Court of Appeals. In four of these cases, the central question was whether state consumer lawsuits would be dismissed because they conflicted with FDA findings. Five of the six cases have been decided. The net result? Consumers’ access to remedies under state laws has, for the most part, been restored.

One of the foundations of these decisions is the principle that congressional intent is paramount. Regulatory agencies cannot, of their own accord, determine pre-emption. These agencies will again have their work enhanced by the additional information provided by discovery and jury trials in common law litigations. The Supreme Court cases are:

- *Riegel v. Medtronic Inc.* An 8-1 decision finding pre-emption of state law product liability claims for certain medical devices. In amending the Federal Food, Drug, and Cosmetic Act with the Medical Device Act, or MDA, Congress expressly reserved device safety to the FDA for all products that go through extensive pre-marketing approval under Section 360. Key in this case was the express pre-emption as part of the MDA.

- *Warner-Lambert Co. LLC v. Kent* . A 4-4 decision affirming, without opinion, the 2nd Circuit’s decision finding a Michigan plaintiff can offer evidence that a drug company defrauded the FDA as a predicate to filing a lawsuit under Michigan statutes. The Supreme Court stated that this decision does not undermine the decision in *Bates v. Dow Agrosciences* that held that state claims of fraud against the FDA were impliedly pre-empted. In Michigan, the proof of fraud was not the cause of action itself but an evidentiary threshold to a cause of action.

• *Exxon Shipping Co. v. Grant Baker* . The Supreme Court limited punitive damages to a ratio of one-to-one with compensatory damages and did not reach the pre-emption issue in this admiralty case.

• *Cuomo v. Clearinghouse* . The issue to be determined is whether 12 USC §484 and 12 CFR §7.4000 prohibit measures taken by the New York State attorney general to enforce State Fair Lending Law against national banks by subjecting those entities to “visitorial powers.” This case is not yet decided.

• *Altria Group Inc. v. Good* . A 5-4 decision that a common law fraud claim, brought under the Maine Unfair Trade Practices Act, was not pre-empted, either expressly or impliedly, by the Federal Cigarette Labeling and Advertising Act.

After *Riegel* , few were hopeful about the future of mass torts as extensive pre-emption seemed likely. The Supreme Court seemed more conservative and pro-business. Several lower courts had found pre-emption in drug cases. The practical effect of these collective decisions was that many firms laid off staff in mass tort departments and planned to reduce their future involvement in the important area of consumer protection litigation. Fortunately, other firms believed that the Supreme Court would not reduce the constitutionally protected police powers of the states to little more than slaves to federal regulators, and entered the fray by supporting *Levine* and her lawyers and by filing amicus briefs. The rights of thousands of citizens lay in the balance.

STATE COURT ACTION ENHANCES PUBLIC SAFETY

Earlier implied or conflict pre-emption decisions looked behind the actual statutory language to divine the purposes and objectives of Congress. Conflict pre-emption means either compliance with a state law, duty or regulation is impossible in light of a federal statute or regulation (*Fidelity Fed. Sav. & Loan Assn. v. De La Cuesta*) or the law or regulation acts as an obstacle to the accomplishment and execution of the purposes and objections of Congress (*Hines v. Davidowitz*) . In *Wyeth* , the majority found that pre-emption based upon “impossibility”

of compliance was a demanding defense that would be applied sparingly and only in a narrow context.

In the second type of conflict pre-emption, “obstacle” pre-emption, the *Wyeth* decision held that the court must perform its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of pre-emption. Some weight may be given to an agency’s views about the impact of state tort law on federal objectives when “the subject matter is technical and the relevant history and background are complex and extensive.” (See *Geier v. American Honda Co.*) The weight accorded, however, depends on the agency’s thoroughness, consistency and persuasiveness in making the proclamation. (See *Skidmore v. Swift & Co.*) In his concurring opinion, Justice Clarence Thomas persuasively argues that federalism invalidates any “obstacle” pre-emption. (See *Atascadero State Hospital v. Scanlon* .)

Read together, these opinions reaffirm the social value of state common lawsuits in advancing consumer safety. This social value should not be overridden in the absence of clear contrary legislative intent. Earlier pre-emption rulings have been clarified. *Wyeth v. Levine* reaffirmed two cornerstones announced in earlier cases: congressional purpose and federalism. “The purpose of Congress is the ultimate touchstone in every pre-emption case.” (*Medtronic Inc. v. Lohr* ; See *Retail Clerks v. Schermerhorn* .) “In all pre-emption cases, and particularly in those in which Congress has legislated ... in a field which the States have traditionally occupied [common law claims], ... we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Wyeth* upheld the presumption against implied pre-emption that the majority in *Riegel* questioned. In the future, implied pre-emption cases will come under heightened scrutiny.

In many of the seminal cases on pre-emption, the factual records lacked the completeness of a full evidentiary trial. Pre-emption motions normally came at the early stages of litigation before the parties had

fully developed the factual context around a federal agency’s decision or process. Until recently, judges lacked vital information necessary to appreciate the interplay between the agencies and companies who appear before them. *Wyeth* was an exception. The case was appealed after a jury verdict for the plaintiff. In *Wyeth* , the court had two factual foundations lacking in the other cases. First, the jury found the warning insufficient. Second, it determined that there was no error by the health care provider. The full record in *Wyeth* made the decision an easier call.

Another factor in the Supreme Court’s decision is recent congressional investigations which have shed light on the limitations of federal agencies in their role as protectors of public safety and provided contextual data supporting the social value of the dual civil justice system envisioned by the Founders more than 200 years ago. These protracted congressional hearings, supplemented by responsible medical opinions from world-class physicians, remove any notion that the FDA, for example, can satisfactorily protect people from serious side effects without the benefit of civil lawsuits. *Wyeth v. Levine* will be remembered as the landmark decision that restored true federalism and the rights of the citizens to enforce safety through individual action in the state courts. •

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