Continued Vigilance Is Warranted

By Daniel J. Gerber

# Federal Preemption after *Wyeth v. Levine*


The United States Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), is one of the most significant federal preemption decisions in the last 20 years. The case was anticipated as a possible unifying opinion that would provide a polestar for lower courts when faced with the offensive or defensive use of federal law or a regulation applying state law. The Court's decision, rejecting preemption on the facts presented, has received mixed reviews. One immediate response upon reading the decision might lead counsel to question the viability of federal preemption in evaluating cases and determining the future course of corporate conduct. This article will explore general preemption principles to provide a backdrop for *Levine*, discuss what was—and what was not—decided by *Levine*, and examine decisions of other courts since *Levine* in similar cases in which the preemption arose.

## The Supremacy Clause and Modern Preemption

Under the Supremacy Clause of the United States Constitution, state regulations yield to federal law when the two conflict. Preemption occurs when federal congressional or agency action defeats state regulation that is inconsistent with either an express or implied exercise of federal power. Preemption is often used as an affirmative defense to attempt to bar state tort actions that rely on a court action by a judge or jury that may contradict federal action.

There are many types of federal preemption. Generally, federal preemption fits into two categories: "express preemption" or "implied preemption." Express preemption occurs when federal law preempts state law within the plain meaning of the text of a statute. *Reigel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006–08 (2008). Implied preemption occurs in three ways. "Field preemption" arises when the federal government's statutes or regulations make it appear that the government intends to occupy an entire regulatory field, leaving no room for state law-making. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230–31 (1947). "Conflict preemption" arises when simultaneous compliance with both state and federal policies is impossible to achieve. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). "Obstacle preemption" occurs when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869–74 (2000).

Whether under express or implied preemption, the scope of state regulation

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preempted may be subject to debate. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 67–68 (2002). Preemption fundamentally rests on congressional intent, best judged through explicit statutory language. *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299 (1988). When implied preemption is at issue, especially in those areas that the states have traditionally regulated, federal congressional intent to supersede state laws must be "clear and manifest." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

During the last two decades, the Supreme Court has weighed in on a wide spectrum of preemption assertions involving topics as diverse as tobacco warnings (*Cipollone v. Liggett Group*, 505 U.S. 504, 112 S. Ct. 2608 (1992), assisted suicide (*Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904 (2006), and a massive oil spill (*Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008), among dozens of preemption cases decided since 1990. In these preemption decisions, judicial philosophies have blurred. Traditionally conservative judges may join those more liberally inclined, under modern definitions, to decide against preemption.

Preceding the Court's decision in *Levine* some trends emerged in its preemption decisions. In express preemption cases, the Court took a more traditional approach of statutory interpretation. The Court read the text of the statute before it and made a decision based on those words or, if the statute was unclear, interpreted the statute using the traditional tools of interpretation, including legislative history. *See, e.g.*, *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008); *Rowe v. New Hampshire Motor Transport Ass'n*, 128 S. Ct. 989 (2008). The decisions typically centered on this theme: "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow AgroSciences*, 544 U.S. 431, 499 (2005).

Implied preemption cases took a different path, largely centered on conventional distinctions between federal and state roles, such as the federal government's role in regulating interstate commerce and directing foreign relations, as opposed to state-based interests. *See, e.g.*, *American Ins. Assn v. Garamendi*, 539 U.S. 396 (2003); *Altria Group v. Good*, 129 S. Ct. 538, (2008); and *English v. General Electric Co.*, 496 U.S. 72 (1990). In *Gade v. Solid Waste Management Assoc.*, 505 U.S. 88, 107 (1992), the court summarized much of the implied preemption doctrine by stating, "The key question is thus at what point the state regulation sufficiently interferes with federal regulation that it should be deemed pre-empted under the Act." *Gade*, 505 U.S. 88, 107 (1992).

> Courts have arguably expanded *Levine*… to allow state law tort claims against generic drug manufacturers.

### *Wyeth v. Levine*: Facts and Opinion

Diana Levine enjoyed her occupation as a guitarist. In April 2000, Ms. Levine felt poorly and went to a clinic. Because she reported nausea, Ms. Levine was given intramuscular injections of a widely used Wyeth product, Phenergan. The first administration of Phenergan did not relieve Ms. Levine's symptoms. Ms. Levine needed a second dose of Phenergan. The second dose was administered through a needle in Ms. Levine's arm.

How the needle was placed in Ms. Levine's arm is unclear. Likely, the administrator intended to place the needle in a vein, which would have been called an "intravenous" (IV) dose. But, by mistake, two things might have happened to make this particular injection the subject of a civil lawsuit, an appeal to the Vermont Supreme Court, and a decision by the United States Supreme Court. First, the needle might have been placed in an artery, not a vein. Second, the needle injection site could have leaked (referred to as perivascular extravasation), which might have resulted in Phenergan reaching an artery in Ms. Levine's arm.

There is little doubt that bad things can happen to good people if Phenergan mixes with arterial blood. Wyeth warned of this possible hazard. The package insert for Phenergan contained the following cautions, warnings, and directions in different sections:

> Under no circumstances should PHENERGAN Injection be given by intra-arterial injection due to the likelihood of severe arteriospasm and the possibility of resultant gangrene (see **WARNINGS—Injection Site Reactions)**.
>
> PHENERGAN Injection should not be given by the subcutaneous route; evidence of chemical irritation has been noted, and necrotic lesions have resulted following subcutaneous injection. The preferred parenteral route of administration is by deep intramuscular injection.
>
> Irritation and damage can also result from perivascular extravasation, unintended intra-arterial injection, and intraneuronal or perineuronal infiltration.
>
> **Inadvertent Intra-Arterial Injection**
> Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or unintentional intra-arterial injection. Reports compatible with unintentional intra-arterial injection of PHENERGAN Injection, usually in conjunction with other drugs intended for intravenous use suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of unintentional intra-arterial injection or perivascular extravasation after it occurs.
>
> INTRA-ARTERIAL INJECTION MAY RESULT IN GANGRENE OF THE AFFECTED EXTREMITY.
>
> The preferred parenteral route of administration for PHENERGAN Injection is by deep intramuscular injection. The proper intravenous administration of this product is well tolerated, but use of this route is not without some hazard. Not for subcutaneous administration.
>
> **UNINTENTIONAL INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED**

**EXTREMITY (see CONTRAINDICATIONS, WARNINGS—Injection Site Reactions). SUBCUTANEOUS INJECTION IS CONTRAINDICATED, AS IT MAY RESULT IN TISSUE NECROSIS (see CONTRAINDICATIONS, WARNINGS—Injection Site Reactions, and ADVERSE REACTIONS).**

Unfortunately, Ms. Levine suffered a terrible consequence after she received the second dose of Phenergan. She developed gangrene, and her forearm was amputated.

Ms. Levine sued in Vermont state court. She sued her health care providers for malpractice. These claims were settled. Ms. Levine also sued Wyeth. The case against Wyeth focused on Wyeth's warnings. Her theory was that the IV-administration method carried such severe risks that the warning label should have prohibited health care providers from considering that option altogether. Ms. Levine won a verdict of $7.4 million.

Wyeth appealed to the Vermont Supreme Court, which affirmed the jury verdict. Wyeth next appealed to the United States Supreme Court with a preemption defense as the central issue on appeal.

In support of its preemption defense, Wyeth argued that the United States Food and Drug Administration (FDA) reviewed Phenergan's label and approved the language. The FDA, Wyeth argued, did not require any change to the label to prohibit IV administration. In fact, FDA directed Wyeth to "retain verbiage" in the label that was the subject of this lawsuit. Wyeth's argument was based on two implied preemption principles. Wyeth concluded that it could not simultaneously comply with the FDA's directions about its warnings and contradictory state jury liability based on those warnings. Wyeth also contended that state law claims based on an allegedly inadequate warning obstructed federal regulation of drug labeling.

The Supreme Court disagreed with Wyeth and decided the jury verdict would stand. The result was disappointing for those looking for a renewed emphasis on implied preemption from the Roberts Court and expansion of the Court's decision in *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).

The Supreme Court decided three important issues for practitioners and courts through its opinion in *Levine*. First, the *Levine* opinion emphasized that the Supreme Court broadly assigned the burden of proof to the party seeking to avoid preemption. Courts will adopt a presumption against preemption, which must be overcome in both express and implied preemption cases. Second, the Court signaled that the "impossibility" of complying with possibly contradictory federal and state regulations must be proven with clear evidence. In this case, for example, Wyeth did not prove either that Wyeth could not have included the more forceful warning about which the plaintiff's experts testified, or that the FDA would not have approved a label change. Third, since Congress or the FDA could have adopted an express statement of preemption and did not do so, the Court determined no proof existed of obstruction of federal regulation. This was especially true in an area so well regulated at the federal level. The national government had ample opportunity to either expressly preempt state tort claims or create policies that implicitly conflicted with state regulation.

> The impact of *Levine* might differ depending on the procedural aspects of a case.

In his concurrence, Justice Thomas forcefully argued against continuing the doctrine of implied preemption. Justice Thomas' position rested firmly in Congress' ability to formulate, in clear terms, within the plain language of a statute, its intention to preempt state tort claims. Without a clearly articulated position in favor of preemption, argued Justice Thomas, given the history of court preemption decisions, no preemption should apply unless clearly expressed by Congress.

## Reaction to *Levine* in the Lower Courts

Many federal district court judges stayed cases pending the outcome in *Wyeth v. Levine*. Because so many courts awaited the decision, a flurry of district court decisions followed through late spring of 2009. Reaction to the *Levine* decision was mixed and illustrates the boundaries of *Levine*'s impact, as well as the front line of battles to come.

Many courts followed the Supreme Court's ruling and found no preemption of state law claims by the applicable federal statutes or remanded cases to trial courts for new proceedings in light of *Levine*'s holding. In pharmaceutical litigation, courts have arguably expanded *Levine*, which dealt with brand-name prescription drugs, to allow state law tort claims against generic drug manufacturers. *See Stacel v. Teva Pharmaceuticals, USA*, 2009 WL 703274 (N.D. Ill. Mar. 16, 2009), *Schrock v. Wyeth, Inc.*, 2009 WL 635415 (W.D. Okla. Mar. 11, 2009), *Kellogg v. Wyeth*, 2009 WL 975382 (D. Vt. Apr. 10, 2009) (all post-*Wyeth v. Levine*, finding no preemption of state law claims against generic-drug manufacturer).

*Levine* was not followed by the Northern District of Ohio in *Longs v. Wyeth*, 2009 WL 754524 (N.D. Ohio Mar. 20, 2009). In *Longs*, the district court contrasted pre-FDA approval claims with post-approval warnings claims. The court also made a distinction between design defect and "fraud on the FDA" claims and the post-market monitoring duty that was the subject of *Wyeth v. Levine*. The *Longs* court said, "While [*Levine*] may stand for the proposition that post-FDA claims are preempted, it does not purport to hold that the same is true for pre-FDA approval claims." *Id.* at *4.

Other cases followed *Levine*, yet found that the relevant federal statue expressly preempted the asserted state law claims. The court in *Bruesewitz v. Wyeth Inc.*, 2009 WL 792468, *19 (3d Cir. Mar. 27, 2009), held that the National Childhood Vaccine Injury Act expressly preempted both strict liability and negligent design-defect claims. The *Bruesewitz* court cited the *Levine* Court, stating that Congress's silence, coupled with its certain awareness of the prevalence of state tort litigation, was powerful evidence regarding the absence of an express preemption provision. The *Bruesewitz* court, however, distinguished the National Childhood Vaccine Injury Act and found that Congress had included an express preemption provision, which was prompted by the prevalence of state tort litigation, as evident in the Committee Report. The *Bruesewitz*

court also distinguished *Levine* by noting that Levine's claim dealt with a drug manufacture's failure to warn of the dangers associated with the drug on its drug label, and a drug manufacture could strengthen a drug label without pre-approval from the FDA. The FDA, however, regarding Bruesewitz's negligent design and defect claims, had far more extensive control and oversight of the approval of a drug's design and alteration.

A few cases unconcerned with state law tort claims have also cited *Levine*, yet found express preemption. In *Pharmaceutical Care Management Ass'n v. District of Columbia*, 2009 WL 711771, *9 (D.D.C. Mar. 19, 2009), the court held that the District of Columbia's AccessRx Act had impermissible connection with ERISA and was, therefore, expressly preempted. The AccessRx Act required pharmacy benefit managers to act as fiduciaries, disclose the content of contracts, and pass on discounts. The court reasoned that because the AccessRx Act "creates the potential for the type of conflicting regulation of benefit plans that ERISA pre-emption was intended to prevent, the AccessRx Act must yield to ERISA's preemptive force." *Id.* Therefore, ERISA preempted the regulations because the regulations impede uniform administration of ERISA plans.

Also, in New *York SMSA Ltd. Partnership v. Town of Clarkstown*, 2009 WL 782971, *4 (S.D.N.Y. Mar. 26, 2009), the court held that a provision of a town ordinance declaring a preference for alternate technologies in evaluating permit applications to install, modify, and renew telecommunication facilities was implicitly preempted by Federal Communications Commission's (FCC) exclusive authority to regulate technical standards for wireless technology under the Telecommunications Act. Further, the court stated that the provision interfered with a field completely occupied by federal law, and the preempted provision could not be severed.

Moreover, the impact of *Levine* might differ depending on the procedural aspects of a case. In *Bradley v. Fontaine Trailer Co., Inc.*, 2009 WL 763548, *5 (D. Conn. Mar. 20, 2009), on the plaintiffs' motion for partial judgment on the pleadings, the court refused to strike the defendant's, a manufacturer, affirmative defenses regarding federal preemption by the Safety Act in a tractor-trailer accident case. In its decision, the court acknowledged the "instructive" nature of *Levine*, but found that since discovery was incomplete, the plaintiffs' claims could still be preempted by the Safety Act. Since the parties were at a preliminary stage of the litigation, the court was unable to decide the fact-intensive question of whether a claim was preempted.

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The plain meaning of the text must stand as the guiding interpretive principle.

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A number of federal appellate courts have considered preemption issues post-*Levine*, but without reference to it. For example, in *Paulsen v. CNF Inc.*, 559 F.3d 1061 (9th Cir. Mar. 20, 2009), the court held that former employees claims for breach of fiduciary duties connected with their loss of retirement benefits were not preempted, either expressly or due to conflict, under the Employee Retirement Income Security Act (ERISA). The court also held that ERISA did not expressly preempt state law professional negligence claims by the plaintiffs against the consulting firm that provided actuarial services for the plan, as those claims neither referred to nor were connected to ERISA plans. The court reasoned that the professional negligence claims were based on common law negligence principles and California statutes, and state law claims did not encroach on ERISA-regulated relationships.

Also, in *Smart v. Local 702 Intern. Broth. of Elec. Workers*, 2009 WL 910970 (7th Cir. Apr. 07, 2009), the court held that the plaintiff's antitrust claim under the Illinois Antitrust Act was preempted by the National Labor Relations Act. The plaintiff was a sole proprietor of a nonunion company that contracted to perform electrical work for construction of a sports complex. He sued the local union, alleging that it coerced the complex owner to terminate its relationship with his company. The court held that the state antitrust claim was completely preempted by the National Labor Relations Act, which provided a means of federal court redress for injuries resulting from a secondary boycott. The court, however, remanded the case to the district court to give the plaintiff an opportunity to amend the claim under the appropriate federal standard.

Similarly, in *Nickels v. Grand Trunk Western R.R., Inc.*, 560 F.3d 426 (6th Cir. Mar. 18, 2009), the plaintiff's state law claims were preempted by the Federal Railway Safety Act (FRSA). The plaintiffs, former railway employees, brought action alleging injuries caused by years of walking on oversized track ballast. The court held that the size of the ballast used to support railroad track was subject to federal regulation, which determined reasonable ballast composition and size for particular track, and thus, FRSA precluded the plaintiffs' Federal Employers' Liability Act claim and the plaintiffs' state negligence actions.

On the other hand, the court in *Campo v. Allstate Insurance Company*, 2009 WL 682619 (5th Cir. Mar. 17, 2009) found that the National Flood Insurance Act did not preempt state law procurement-based claims brought by the plaintiff against his insurer for allegedly negligent misrepresentations. The plaintiff sued his insurer as a Write-Your-Own Program carrier participating in the National Flood Insurance Program (NFIP). He alleged that the insurer and its representatives made negligent misrepresentations that prevented him from renewing his flood insurance policy. The court held that the federal law did not preempt the plaintiff's claims because Congress, in delegating regulatory power to Federal Emergency Management Agency (FEMA), had expressly preempted state law only for handling-related claims. Therefore, it found the plaintiff's claim permissible, since it did not concern handling.

In *Pet Quarters, Inc. v. Depository Trust and Clearing Corporation*, 559 F.3d 772 (8th Cir. 2009), the plaintiffs' misrepresentation-related state law claims were implicitly preempted under conflict preemption. The plaintiffs, a pet supply business and several of its shareholders, sued in state court, alleging that a stock-borrow program created and operated by Depository Trust and Clearing Corporation and its subsidiaries drove down the market price for its shares

and eventually put it out of business. The court held that the plaintiffs' misrepresentation state law claims directly challenged program rules approved by Securities and Exchange Commission (SEC) under its statutory power to regulate clearing agencies. Thus, the plaintiffs' claims were federally preempted under conflict preemption. The court reasoned that all of the damages that the plaintiffs' alleged that they suffered stemmed from activities performed or statements made by the defendants in conformity with the program's Commission-approved rules.

### Advising a Client after *Levine*

Federal regulations that can be interpreted as minimum guidelines or baseline standards have not been well-received by the Supreme Court as a basis for federal preemption. *See Sprietsma*, 537 U.S. 51, 67–68 (2002) (Federal Boat Safety Act (FBSA) did not expressly or implicitly preempt common-law tort claims, arising out of failure to install propeller guards on motorboat engines); *Bates*, 544 U.S. 431, 499 (2005) (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) did not preempt claims for defective design, defective manufacture, negligent testing, breach of express warranty, and violation of Texas Deceptive Trade Practices Act, *Exxon Shipping Co.*, 128 S. Ct. 2605 (2008) (Clean Water Act, a statute expressly geared to protecting "water," "shorelines," and "natural resources," was not intended to eliminate sub silentio oil companies' common law duties to refrain from injuring the bodies and livelihoods of private individuals).

In *Levine*, the defendant did not sway the Court that the Federal Food, Drug and Cosmetic Act provisions at issue provided a standard or mandate from which Wyeth could not stray. *Compare Reigel v. Metronic, Inc.*, 128 S. Ct. 999, 1006–08 (2008) (FDA premarket approval process established federal requirements, and patient's New York common law claims of negligence, strict liability, and implied warranty against the manufacturer were preempted); *Gade*, 505 U.S. 88 (1992) (Illinois' licensing acts were preempted by the Occupational Safety and Health Act's occupational safety and health standards for training those working with hazardous waste, since neither of act's savings provisions were implicated, and Illinois did not have a plan approved by the U.S. Secretary of Labor); *Geier*, 529 U.S. 861, 869–74 (2000) (defective design action was preempted since it conflicted with a U.S. Department of Transportation standard requiring manufacturers to place driver-side airbags in some but not all 1987 automobiles). Therefore, counsel must question whether an action is prohibited or determined by federal regulation before asserting a preemption defense. If so, counsel must be prepared to prove that the federal action made compliance with state regulation impossible. If it has not, preemption defenses are less likely to succeed.

> Courts will likely adopt, for the near future, a presumption against preemption.

As with all regulations, the plain meaning of the text must stand as the guiding interpretive principle. Express and implied preemption are intertwined, at this point, given the sophistication of federal regulation and the well-recognized principles of preemption. Courts may be predisposed to accept joint federal and state regulation as implicit, without an express preemption provision. Without an expressly stated policy of preemption, courts may wonder whether implied preemption can be extrapolated in areas of traditional state regulation, such as tort law.

Counsel may consider, either in anticipation of state regulation or civil claims, whether seeking federal regulatory action is beneficial for long-term stability and predictable outcomes. For example, if Wyeth had explicitly proposed a change to the Phenergan label to prohibit IV administration and the FDA had rejected the change, the result would likely have differed, even if the FDA had rejected the change after initiation of the civil case. The Supreme Court has not specified a method of proof of anticipated FDA-rejection of a label change premised on clear evidence. There is reason to believe an actual rejection (as difficult as that may be to achieve), even one post-verdict, might have an effect on a preemption defense.

Courts will likely adopt, for the near future, a presumption against preemption. Counsel should be aware, in attempting to predict judicial decisions on preemption defenses, that the party seeking preemption has both the legal and factual burden of proof. Further, counsel opposing preemption may consider more aggressive action to obtain summary judgment against these defenses.

As sweeping as *Wyeth v. Levine* may have been, though, the opinion is likely more limited in scope than many opposing preemption will admit. In the flurry of post-*Wyeth* decisions, lower courts have demonstrated that the case's applicability may be limited to post-market labeling changes that arise from adverse event signals. *Buckman*, *Riegel* and *Geier*, for example, still uphold the proposition that federal regulatory approval of product designs and an overall federal regulatory system approval and disapproval of certain actions may stand as proof of federal predominance sufficient to prevail on a preemption claim. Counsel can point out that the Supreme Court in *Levine* did not explicitly overrule any significant previous preemption decision in its opinion.

### Conclusion

Corporate counsel and outside counsel must remain vigilant in counseling clients on sophisticated preemption issues. The United States Supreme Court and other federal courts will continue to refine the contours and boundaries of preemption doctrines over time. The Roberts Court has shown a reluctance to overturn precedent thus far, focusing instead on creating internal consensus on the most narrow issues to be decided. If this trend continues, *Wyeth v. Levine* may become less significant over time as its holding becomes limited to the most narrow issues presented. However, counsel should be mindful that the Supreme Court's decision may influence courts to more narrowly construe both express and implied preemption. In the short term, arguments both for and against preemption based on the decision must be considered carefully.