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Federal Pre-Emption After Wyeth v. Levine Analyzing the Supreme Court's Sweeping New Decision; Implications for Product Liability Litigation

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Wyeth v. Levine

Presentation by
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Wyeth v. Levine – Majority Opinion

- Factual Background
- Justice Stevens' opinion
 - Two settled facts
 - Two “cornerstone” principles of preemption law
 - Impossibility preemption: a “demanding defense”
 - Obstacle preemption: the agency's view “does not merit deference”

Wyeth v. Levine – Concurrences

- Justice Breyer's concurrence
 - Emphasizes that *Wyeth* did not involve a regulation bearing the force of law
- Justice Thomas's concurrence
 - Concurs in the judgment only
 - Agrees with the majority's analysis of impossibility preemption
 - Disavows obstacle preemption as “inherently flawed”

Wyeth and other preemption cases

- Recent Supreme Court decisions
 - *Altria Group Inc. v. Good*
 - “Light” cigarette case
 - No express or implied preemption
 - *Riegel v. Medtronic, Inc.*
 - Medical devices case
 - Express preemption
 - *Watters v. Wachovia Bank, N.A.*
 - Banking regulation
 - State law conflicts with statute

Wyeth and other preemption cases

- Lessons from the recent cases
 - The specific statute and regulatory regime matter
 - The presumption against preemption is alive and well
 - The Court's past practice of following the Government's views in preemption cases may be waning

Wyeth and other preemption cases

- *Cuomo v. The Clearing House Ass'n, LLC*
 - Set for argument April 28, 2009
 - Second Circuit deferred to Comptroller regulation preempting state enforcement of *non-preempted* state law
 - The Comptroller's reasoning in support of the regulation is based on its interpretation of relevant legal decisions
 - The Government has filed a brief in support of preemption

U.S. Supreme Court Rejects Federal Preemption of Failure-to-Warn Claims in Absence of “Clear Evidence” that FDA Would Not Have Approved Stronger Warnings

The United States Supreme Court issued on March 4, 2009 its much-anticipated decision on federal preemption of failure-to-warn claims against pharmaceutical manufacturers in *Wyeth v. Levine*. Slip op., No. 06-1249 (Mar. 4, 2009).¹ The Court rejected the preemption defense on the specific facts of that case, but left open its application in future cases where the record reflects “clear evidence” that the FDA actively oversaw the labeling and the specific risk at issue in the case. The Court also left other preemption doctrines, such as the rejection of “fraud on the FDA claims,” unchanged.

Background

Levine began when the plaintiff received an IV-push injection of the drug Phenergan, an anti-nausea drug, from a physician assistant. The drug entered the plaintiff's artery, either because the needle penetrated the artery or because the drug escaped from the vein into the surrounding tissue and came in contact with arterial blood. As a result, the plaintiff developed gangrene, which later necessitated amputation of her right hand and eventually her entire forearm. The drug's label warned about the risk of gangrene from inadvertent intra-arterial injections, but did not specifically contraindicate IV-push injections. A jury found

the manufacturer negligent and Phenergan defective because the label did not give an adequate warning of the risk from IV-push injection. The jury awarded the plaintiff \$7.4 million, which was subsequently reduced by the court to account for earlier settlements the plaintiff had reached with the physician assistant and health center where she was treated.

The manufacturer appealed, arguing on two separate grounds that the plaintiff's claims were impliedly preempted by federal law because the FDA had approved the label. First, it would have been impossible for the manufacturer to comply with the jury-imposed, state-law duty to give a stronger warning against IV-push administration of Phenergan without violating federal law. Second, the state-law action creates an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”² The majority opinion in *Levine*, written by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg, and Breyer, rejected both arguments.

² See *Hines v. Davidowitz*, 312 U.S. 52 (1941).

¹ The opinion is available at www.supremecourtus.gov/opinions/08pdf/06-1249.pdf.

Impossibility Preemption

As to “impossibility preemption,” the majority held that the manufacturer could have complied with both the jury’s mandate and federal law by availing itself of the FDA’s “changes being effected” (“CBE”) regulation. The CBE regulation is an exception to the default rule requiring the FDA to pre-approve a drug’s label. It provides that if a manufacturer is changing a label to “add or strengthen a contraindication, warning, precaution, or adverse reaction” or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” the manufacturer may make the labeling change upon filing a supplemental application with the FDA and need not wait for FDA approval.³ But the CBE regulation is limited. A 2008 amendment, which merely codified the FDA’s prior policy, provides that a manufacturer may only change its label “to reflect newly acquired information.”⁴

In *Levine*, the manufacturer argued that there was no new information about Phenergan that justified a CBE amendment. The majority disagreed, explaining that “‘newly acquired information’ is not limited to new data, but also encompasses ‘new analyses of previously submitted data’.” Slip op. at 12 (Majority Opinion). The “rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments.” *Id.* Thus, according to the majority, “[i]n later years [after the first case of gangrene and amputation was reported in 1967], as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug.” *Id.*

The majority necessarily acknowledged that “the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer’s supplemental application. . . . But absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.” *Id.* at 15. In a

³ 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

⁴ 73 Fed. Reg. 49609.

key passage, the majority explained this point as follows:

Wyeth has offered no such evidence. It does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA. And while it does suggest that the FDA intended to prohibit it from strengthening the warning about IV-push administration because the agency deemed such a warning inappropriate in reviewing Phenergan’s drug applications, both the trial court and the Vermont Supreme Court rejected this account as a matter of fact. In its decision on Wyeth’s motion for judgment as a matter of law, the trial court found “no evidence in this record that either the FDA or the manufacturer gave more than passing attention to the issue of” IV-push versus IV-drip administration. The Vermont Supreme Court likewise concluded that *the FDA had not made an affirmative decision* to preserve the IV-push method or intended to prohibit Wyeth from strengthening its warning about IV-push administration. Moreover, Wyeth does not argue that it supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method. We accordingly cannot credit Wyeth’s contention that the FDA would have presented it from adding a stronger warning about the IV-push method of intravenous administration.

Id. at 16 (emphases added).

The majority then concluded: “[o]n the record before [it] . . . Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements.” *Id.*

Purposes and Objectives Preemption

As to “purposes and objectives preemption,” the majority rejected the manufacturer’s argument that “the FDCA establishes both a floor and a ceiling for drug regulation.” *Id.* at 17. In so doing, it relied upon two keys facts. First, Congress never enacted an express preemption provision, despite its awareness of the prevalence of state tort litigation and its enactment of an express preemption provision for medical devices. *Id.* at 18.

Second, the manufacturer's reliance on the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels was misplaced.⁵ The preamble expressly stated the FDA's view that the FDCA establishes "both a 'floor' and a 'ceiling,'" such that "FDA approval of labeling . . . preempts conflicting or contradictory State law."⁶ However, when the FDA finalized the rule in 2006, it never offered "States or other interested parties notice or opportunity for comment." Slip op. at 21 (Majority Opinion). Because the FDA did not allow such notice and comment, the majority concluded that the preamble was "inherently suspect" and did not deserve any deference. *Id.* Instead, the majority found that the FDA "traditionally regarded state law as a complementary form of drug regulation" that is no obstacle to the purposes and objectives of federal law. *Id.* at 22.

The Concurring Opinions

In addition to Justice Stevens' majority opinion, there were two noteworthy concurrences. Justice Breyer, who also joined in the majority opinion, wrote separately to emphasize that if the FDA were to engage in formal rulemaking on this issue in the future, such future regulations might have preemptive effect.

Justice Thomas, who did not join in the majority opinion and thus only concurred with the judgment, explained his view that only impossibility preemption is a constitutionally valid judicial inquiry. Purposes and objectives preemption, in his view, too often leads to the invalidation of state law based upon "broad federal policy objectives, legislative history, or generalized notions of Congressional purposes that are not embodied within the text of federal law," and, therefore, "are inconsistent with the Constitution." Slip op. at 2 (Justice Thomas' Concurring Opinion).

The Dissent

The dissenting opinion, authored by Justice Alito and joined by Chief Justice Roberts and Justice Scalia, is significant because it dramatically illustrates that the key disagreement with the majority was the proper view of the factual record.

⁵ See 71 Fed. Reg. 3922 (2006).

⁶ *Id.* at 3934-35.

In stark contrast to the majority opinion, the dissent argued that "the record contains ample evidence that the FDA specifically considered and reconsidered the strength of Phenergan's IV-push related warnings in light of new scientific and medical data." Slip op. at 9 (Dissenting Opinion). This evidence included meetings between the manufacturer and FDA as far back as 1975, the convening of an advisory committee to study, *inter alia*, the IV-push issue, and a thoroughly researched and supported labeling order in 1987. *Id.* at 10-14. Thus, according to the dissent, "it cannot be said that the FDA 'paid no more than passing attention to' IV push; nor can it be said that the FDA failed to weigh its costs and benefits." *Id.* at 16 (*quoting* Slip op. at 6 (Majority Opinion)).

The dissent also viewed differently the question of whether jury verdicts based on alleged failures to warn are an obstacle to the purposes and objectives of federal law. According to the dissent, "juries are ill-equipped to perform the FDA's cost-benefit-balancing function" because they "tend to focus on the risk of a particular product's design or warning label that arguably contributed to a particular plaintiff's injury, not on the overall benefits of that design or label." *Id.* at 23.

Implications

The Supreme Court has not precluded manufacturers from asserting federal preemption as a defense in future failure-to-warn cases. The majority opinion acknowledges that on a different record—one that demonstrates "clear evidence" that the FDA "gave more than passing attention" to the specific risk at issue and/or made an "affirmative decision" that additional warnings would be inappropriate—the CBE regulation would be rendered moot and impossibility preemption might apply. There are complex questions to be resolved by lower courts regarding the nature, presentation, and quantum of such evidence necessary to establish the defense, but given the FDA's active oversight of labeling decisions, there is a strong argument that the defense will apply in some circumstances.

Moreover, *Levine* does not address or change other preemption theories that manufacturers commonly assert in product liability litigation. For example, the "fraud on the FDA" theory remains viable as a result of the Supreme Court's decision in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). Similarly, consistent with the Supreme Court's decision last year in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999

(2008), express preemption theories are still available and remain unchanged by *Levine* (though there has been legislation introduced in Congress to overrule *Riegel*). And since *Levine* only involved preemption of inadequate warning claims, the ruling did not address design defect or other non-warning allegations. Given the requirement that the FDA affirmatively establish the safety and effectiveness of all new drugs before approving them, preemption issues in design-related claims implicate FDA processes more closely analogous to those the Court addressed in *Riegel* than in *Levine*.

Finally, as emphasized by Justice Breyer's concurrence, future rulemaking by the FDA could formally promulgate the principles it informally articulated in the 2006 preamble, and thus change the preemption analysis.



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The U.S. Supreme Court's *Wyeth v. Levine* decision limits the availability of preemption and sets ground rules for future litigation regarding the scope of that defense, attorneys James M. Beck and Mark Herrmann say in this Analysis & Perspective.

In reaching its decision, the Court answered some questions and created others. The authors analyze the Supreme Court's majority ruling and discuss what types of cases might survive preemption.

After *Levine*, one thing is absolutely certain, the authors say: "The availability of preemption in tort suits involving prescription drug labeling now will turn almost exclusively upon what the FDA has said about the specific warnings and specific risks involved in litigation. Conversely, the implied preemption debate will proceed without much attention to what the FDA has said about preemption itself."

***Wyeth v. Levine* Restricts Preemption in Prescription Drug Litigation**

By JAMES M. BECK AND MARK HERRMANN

In *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (U.S. March 4, 2009), the U.S. Supreme Court ruled, by a 6-3 vote, that approval of prescription drug labeling by the Food and Drug Administration (FDA)

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does not preempt state law tort claims "absent clear evidence that the FDA would not have approved a [label] change" along the lines advocated by the plaintiff. *Id.* at *9. The *Levine* decision thus restricts the availability of preemption and defines the ground rules for future litigation over the scope of that defense.

Diana Levine was a children's guitarist in Vermont. In April 2000, she went to a clinic for treatment of a severe migraine headache and associated nausea. She was originally treated with *intramuscular* injections of Demerol (for headache) and Wyeth's drug, Phenergan (for nausea). Intramuscular injection was the preferred method for administering Phenergan identified in the product's labeling.

When that treatment did not provide relief, Levine returned to the clinic, and a physician's assistant administered a second dose of Demerol and Phenergan *intravenously* by IV push injection—injecting the medication into the tubing of an IV infusion set that led to a needle inserted into what the assistant thought was a vein.

At the time of Levine's treatment, the package insert for Phenergan warned in several places about the risk of gangrene arising from inadvertent exposure of arterial blood to the drug. Among other things, the "Adverse Reactions" section of the label said, in bold, upper-case letters: "INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY."

The FDA had regularly reviewed Wyeth's labeling for Phenergan, and the agency was aware of the risk of gangrene if arterial blood is exposed to the drug. In 1997 (the last review before Levine's treatment), the FDA ordered Wyeth to make various changes to the labeling of Phenergan, but directed the company to "[r]etain verbiage in current label" about inadvertent intra-arterial injection.

Unfortunately, after Levine's treatment, she developed the symptoms of arterial exposure and gangrene, requiring amputation of her forearm.

Levine sued the health clinic, physician's assistant, and supervising physician for malpractice, and she settled those claims for \$700,000. She then sued Wyeth in state court in Vermont, pleading state law claims for inadequate warning. At trial, Levine's lawyer and expert witness both argued that Wyeth should have contraindicated intravenous injection of Phenergan on the drug's label, forbidding that method of administration—even though the FDA never required such a contraindication and instead required Wyeth to use only the language the agency had approved.

Wyeth asserted the defense of federal preemption, arguing that state tort law could not find defective a warning that the FDA had approved. The trial court rejected Wyeth's argument, and the jury entered a verdict of \$7.4 million against Wyeth. The judgment was later reduced to \$6,774,000 to account for prejudgment interest and the settlement of the earlier malpractice suit. The Vermont Supreme Court affirmed the trial court judgment, and the U.S. Supreme Court again affirmed.

Court Rejects Broad Preemption Argument

The Supreme Court rejected Wyeth's argument for broad preemption—also advocated by the Solicitor General on behalf of the FDA—that "[o]nce the FDA has approved a drug's label, a state law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Levine*, 2009 WL 529172, at *10. *Levine* rejected two different bases for recognizing a broad implied preemption defense. First, there is no broad preemption under the rubric of "impossibility":

Impossibility pre-emption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change.

Id. at *9.¹ Second, the Court rejected the proposition that state-law inadequate warning claims broadly obstruct the purposes or objectives of the federal regulatory scheme for drug labeling:

Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight.

Id. at *13. The Court did not intend to foreclose implied preemption by reason of conflict between the requirements imposed by the FDA and those imposed by state tort law. The Court "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives." *Id.* *Levine* itself, however, was "not such a case." *Id.*²

Questions Answered, Questions Raised

In reaching its decision, the Court answered some questions and created others. The Court's holdings include:

- The so-called "presumption against preemption" applies to implied preemption cases. 2009 WL 529172, at *5.
- For both implied and express preemption analysis, "the purpose of Congress is the ultimate touchstone." *Id.*
- There is no preemption by reason of physical impossibility where a drug manufacturer can strengthen its warnings without prior FDA approval on the basis of "new analysis" of data "previously submitted" to the Agency. *Id.* at *7.
- Under the Federal Food, Drug and Cosmetic Act, "the manufacturer bears responsibility for the content of its label." *Id.* at *8. Thus, as long as the FDA has not "prohibit[ed]" a different or stronger warning, there is no impossibility preemption.
- Lack of express preemption can inform the implied preemption analysis where congressional "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation," indicates the absence of preemptive intent. *Id.* at *10.
- In view of the "longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies," there was insufficient evidence of any obstacle to federal objectives to support preemption. *Id.* at *13.

¹ "CBE" stands for "changes being effected," which describes the FDA regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A, C), permitting manufacturers to strengthen warnings and similar cautionary statements under certain circumstances without prior FDA approval, but subject to the risk of later adverse FDA action.

² Justice Stephen Breyer concurred to emphasize that the FDA could validly address the preemptive scope of its organic statute by formal regulation. *Id.* at *13. Justice Clarence Thomas concurred in the result reached by the five-justice plurality, but not in their reasoning. His opinion advocated abolishing implied preemption by reason of obstruction of federal purposes and objectives. *Id.* at *21-24. Justice Samuel A. Alito Jr., joined by the Chief Justice and Justice Antonin Scalia, dissented, and would have found the plaintiff's claims preempted because they amounted to a "duty to contraindicate" an FDA-approved indication. *Id.* at *26, 30-33.

**Levine represents the Waterloo of the Bush
Administration FDA's attempt to induce the courts
to apply preemption broadly in prescription drug
tort litigation.**

In addition to these legal points, *Levine* represents the Waterloo of the Bush Administration FDA's attempt to induce the courts to apply preemption broadly in prescription drug tort litigation. The preemption controversy that produced the *Levine* decision was in large part prompted by the FDA's promulgation, in early 2006, of a final rule that in its preamble contained an expansive view of preemption. See 71 Fed. Reg. 3922 (FDA Jan. 26, 2006). *Levine*, in marked contrast to precedent,³ gave the FDA's position "no weight" at all, largely because the agency's position contradicted its previous statements about preemption and the relationship of tort law to the regulatory scheme it superintended.⁴ 2009 WL 529172, at *11-13. The Court found the FDA's position "suspect" for both procedural and substantive reasons:

[T]he agency finalized the rule . . . without offering States or other interested parties notice or opportunity for comment. . . . The agency's views on state law are inherently suspect in light of this procedural failure. Further, the preamble is at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence.

Id. at *11-12. The Court gave more credence to the views of former FDA officials than it did to the current position of the FDA itself as stated in both the *Federal Register* and the Solicitor General's amicus curiae

³ In prior tort preemption cases, involving both express and implied preemption, the Supreme Court almost always reached the result advocated by the relevant federal agency. See *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) (finding implied, but not express, preemption in accordance with views of the Solicitor General); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (same); *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008) (finding express, but not implied, preemption in accordance with the views of the Solicitor General); *Altria Group Inc. v. Good*, 129 S. Ct. 538 (2008) (finding no preemption in accordance with the views of the Solicitor General); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (same); *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996) (same); but see *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) (finding less express preemption than Solicitor General advocated).

⁴ In previous cases, the Supreme Court has deferred to the positions advocated by federal agencies, even when those positions changed over time. Thus, in *Riegel*, the Supreme Court found express preemption in accordance with an FDA position that was diametrically opposed to the agency's views some years earlier. 128 S. Ct. at 1009. Likewise, in *Altria v. Good*, the Court found "more telling" an agency's recent decision that rescinded a prior guidance that had been in effect for more than 30 years. 129 S. Ct. at 551.

brief.⁵ Rarely, if ever, has the Supreme Court so thoroughly rejected a position advocated by a federal agency, at least on the subject of preemption.

Nonetheless, even after *Levine*, pharmaceutical manufacturers are better off with respect to preemption than they were before the FDA spoke in 2006. Before 2006, courts had refused to find preemption by reason of conflict with FDA regulations even where a particular tort claim directly contradicted an affirmative FDA decision involving the precise risk in question.⁶ Nothing in *Levine* suggests a retreat of that magnitude.

That some level of implied preemption survives *Levine* is almost immediately evident from the majority's treatment of the "failure to contraindicate" issue. The record established that one theory submitted to the jury was that the drug's label should have contraindicated—flatly prohibited—"IV-push" injection, which was the method of administration in the case.⁷ There was apparently not a majority in the Supreme Court for holding that a "failure to contraindicate" claim could survive preemption. The Court thus struggled to treat the case as involving run-of-the-mill failure to warn. *Id.*⁸ The Court concluded that the existing warnings, such as "INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY," could somehow have been strengthened, but not converted into a contraindication, in a way that would have avoided *Levine*'s injury.⁹

Scope of Preemption Post-*Levine*

Right off the bat, the *Levine* majority implicitly concedes (and the dissent concludes) that a tort claim alleging that a defendant should have contraindicated an FDA-approved use of a drug would be preempted.

The scope of preemption in prescription drug tort litigation after *Levine* appears to extend well beyond contraindication claims. At several points in its opinion, the Court discusses and distinguishes situations involving particularized FDA involvement in drug labeling—providing some guidance as to what "state-law claims might well frustrate the achievement of congressional

⁵ *Levine*, 2009 WL 529172, at *12 n.12 (quoting with approval from amicus brief and law review article written by former FDA commissioners).

⁶ See, e.g., *Feldman v. Lederle Laboratories*, 479 A.2d 374, 379, 389-90 (N.J. 1984) (no preemption despite FDA forbidding warning that drug in question caused injury at issue); *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1091-94 (C.D. Cal. 2000) (no preemption despite FDA concluding that insufficient scientific evidence existed to justify warning that the drug caused the injury at issue); *In re Tetracycline Cases*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989) (same as *Feldman*).

⁷ 2009 WL 529172, at *5 (plaintiff "also offered evidence that the IV-push method should be contraindicated and that Phenergan should never be administered intravenously"); see also *id.* at *26 (dissent detailing plaintiff's claims at trial).

⁸ The majority relied upon a footnote by the Vermont Supreme Court maintaining "any number of ways for [defendant] to strengthen the Phenergan warning without completely eliminating IV-push administration." 2009 WL 529172, at *5 (quoting *Wyeth v. Levine*, 944 A.2d 179, 189, n. 2 (Vt. 2006)).

⁹ See 2009 WL 529172, at *31 (dissent quoting warning, which is omitted from majority opinion). The Court's reasoning left other legal loose ends, too. The question whether a general verdict can be affirmed when it was based in part upon a legally invalid theory (failure to contraindicate) was a matter of state law not addressed by the court below.

objectives.” 2009 WL 529172, at *13. The Court noted that:

- The defendant did not offer evidence that it was impossible to reanalyze its accumulated adverse experience reports to fit within the “new analyses of previously submitted data” provision of the post-2008 changes being effected regulation. *Levine*, 2009 WL 529172, at *7-8.
- There was no “clear evidence that the FDA would not have approved a change to [the drug’s] label.” *Id.* at *9.
- The defendant did not “attempt [] to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA.” *Id.*
- The defendant “does not argue that it supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method.” *Id.*
- Unlike *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), in *Levine* there was no “formal rulemaking” followed by an agency “plan” that “revealed the factors the agency had weighed and the balance it had struck.” 2009 WL 529172, at *12.
- “[W]e have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law.” *Id.*
- The record “belie[s]” the contention that “the FDA determined that no additional warning . . . was needed, thereby setting a ceiling on [the] label.” *Id.* at *13 n.14.

Thus, to the extent that the FDA has specifically considered and rejected a stronger warning about the risk in question, *Levine* suggests that claims advocating the rejected labeling would be preempted. Similarly, if the FDA ultimately refused or required significant modification of a warning change initiated by CBE, then there are good grounds for arguing, after *Levine*, that tort claims premised on the submitted label change would be preempted. Drug manufacturers concerned about litigation and hoping to maximize a preemption defense should adjust their regulatory behavior accordingly.¹⁰ Affirmative, specific FDA action is the best scenario for preemption in prescription drug tort litigation after *Levine*.

Other possibilities for prevailing on a preemption defense may also exist. *Levine* emphasized the availability of CBE labeling changes. However, as the Court noted, 2009 WL 529172, at *7, the CBE regulation, § 314.70(c)(6)(iii), was recently amended. A manufacturer who can demonstrate that available data did not

¹⁰ While formal, drug-specific notice-and-comment rule-making is also mentioned in *Levine*, in practice that is too remote a possibility to be considered seriously.

support a CBE submission, can argue that a tort claim premised on such a change is preempted.¹¹ Other “clear evidence” that a particular label change would not have been approved—such as a recent FDA decision to adopt other language concerning a particular risk, or an independent FDA-sponsored analysis of relevant data—would also support a preemption argument. There are probably other scenarios that would support preemption after *Levine*, given the many avenues of FDA review provided by the statute and the agency’s regulations.

Nor, for that matter, does *Levine* address anything other than labeling claims. Other types of claims—for design defect, or nuisance claims against manufacturers of approved drugs, or claims that a drug should never have been approved in the first place—more strongly implicate the FDA’s core function of determining the safety and effectiveness of all marketed drugs. Those claims implicate the risk/benefit calculation that the FDA performs when it initially approves a drug, and thus raise preemption issues that resemble the policy basis of the Court’s express preemption decision in *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008). *Levine* does not say a word about non-warning claims, nor does it impair the Court’s unanimous ruling in *Buckman* that fraud-on-the-FDA claims are preempted.

Finally, *Levine* has at least one non-preemption implication that is helpful for defendants. The Court stated, “Because the statute contemplates that federal juries will resolve most misbranding claims, the FDA’s belief that a drug is misbranded is not conclusive.” 2009 WL 529172, at *8. There is thus even less reason than before for courts to admit FDA warning letters, untitled letters, Forms 483, and the like into evidence in civil litigation. According to *Levine*, bare agency statements made in those documents contain no conclusions that a court is bound to respect. *Levine* should thus reduce substantially the “probative value” of those documents under Federal Rule of Evidence 403.

After *Levine*, one thing is absolutely certain. The availability of preemption in tort suits involving prescription drug labeling now will turn almost exclusively upon what the FDA has said about the specific warnings and specific risks involved in litigation. Conversely, the implied preemption debate will proceed without much attention to what the FDA has said about preemption itself.

¹¹ The Court pointed to 20 adverse event reports involving Phenergan and the risk of gangrene and amputation. 2009 WL 529172, at *8. The label, however, had been in effect for some 30 years. If the record had contained analysis showing no statistically significant increased risk, then a CBE submission may not have been possible.