DechertOnPoint

March 2009 / Issue 48

A legal update from Dechert's Mass Torts and Product Liability Group

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.

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

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

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 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.

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

4 73 Fed. Reg. 49609.

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.

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

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5 *See* 71 Fed. Reg. 3922 (2006).

6 *Id.* at 3934-35.

(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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