

WYETH V. LEVINE: NOT THE END OF PREEMPTION AND NOT THE END OF THE WORLD

March 10, 2009

To Our Clients and Friends:

On March 4, 2009, the Supreme Court of the United States issued its decision in the closely watched case, *Wyeth v. Levine*. In a 6-3 opinion authored by Justice Stevens, the Court held that federal law did not preempt the plaintiff's claim pursuant to state law that the label of the anti-nausea drug Phenergan did not contain an adequate warning of the risks associated with "IV-push" administration of the drug. The plaintiff had gone to a clinic for treatment of a migraine headache; a physician's assistant administering Phenergan via IV-push (rather than the safer IV-drip or intramuscular injection methods) introduced the drug into her artery, resulting in gangrene and the amputation of her forearm and hand. The plaintiff alleged that her injury would not have occurred if Phenergan had carried an adequate warning against administration via IV-push. A Vermont jury agreed and awarded her \$6.7 million.

As described by the Supreme Court, Wyeth made two arguments in favor of implied preemption: (1) that it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law, and (2) that recognition of the plaintiff's state law tort action creates an "unacceptable obstacle to the accomplishment and execution of the full purposes of Congress" underlying the Food, Drug and Cosmetic Act. Impossibility preemption, as the majority acknowledged, is a "demanding defense." The majority found that Wyeth was unable to meet those demands, particularly in light of regulations permitting a manufacturer to add safety information to a label in advance of FDA approval of the additional information. The Court further found no support for the proposition that Congressional purposes would be frustrated by the plaintiff's failure to warn suit where the FDA had repeatedly (until it changed course in 2006) indicated that it did not believe that state tort law claims would frustrate its mission or that states were precluded from imposing additional labeling requirements above the FDA floor.

The Supreme Court decision was undoubtedly a defeat for Wyeth and a setback for the pharmaceutical industry, which had enjoyed a previous streak of largely consistent preemption victories. In the hours and days after the decision was released, however, the decision was variously characterized as "a landmark, much-needed victory for all consumers" (*Business Wire*), a "strong signal to lower court judges to let state liability lawsuits go forward even when the federal government regulates the area" (*USA Today*), and even an occasion to

“Let the Plaintiffs’ Rejoicing Begin!” (*AmericanLawyer.com*). The actual impact of the decision will of course unfold over time, but these characterizations seem to greatly overstate the likely effect of the decision.

WHAT WYETH IS AND IS NOT

First, *Wyeth* is an implied preemption case. The Food, Drug and Cosmetic Act does not contain an express preemption provision with respect to prescription drugs; indeed, the Court found significant that the 1962 amendments added a “savings clause,” which indicated that a provision of state law would only be invalidated upon a “direct and positive conflict” with the FDCA. *Wyeth* thus has no application to preemption questions involving federal statutes with express preemption clauses and/or without savings clauses. Notably, *Wyeth* has no effect on preemption under the Medical Device Amendments to the FDCA because the MDA contains an express preemption provision.

Second, *Wyeth* explicitly distinguishes implied preemption analysis where there is an “FDA regulation bearing the force of law.” The Court strongly suggested that an FDA regulation involving formal rulemaking might well have preemptive effect as the airbag regulations did in *Geier v. American Honda Motor Co.* In *Wyeth*, the only positive FDA regulation at issue was a 2006 preemption preamble added to an FDA rule without notice or opportunity for comment. The preamble did not actually address the substantive labeling of Phenergan or any other drug but simply stated, *ipse dixit*, “FDA approval of labeling . . . preempts conflicting or contrary State law.” The Court was disinclined to defer to this pronouncement, given the procedural flaws that led to it and the fact that it reversed the FDA’s own position regarding preemption at various times relevant to the litigation.

Finally, the Court noted, somewhat tartly, the trial court’s determination that there was “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 of Phenergan. The Court thus left open the question of implied preemption in a context in which there was evidence that the FDA balanced competing objectives, including the risk that materialized in the litigation at issue, before approving or mandating a particular label. Where a label has been subject to deliberative decision-making (and perhaps more recent updating), *Wyeth* suggests that a state law claim might be more likely to be preempted.

PRACTICAL IMPLICATIONS OF THE DECISION

Contrary to the opinions of some commentators, *Wyeth* did not sound the death knell on implied conflict preemption. In fact, the Court closed the opinion by confirming that “we recognize that some state law claims might well frustrate the achievement of congressional objectives” and thus be subject to implied preemption. An outline seems to emerge from

Wyeth of the situation in which the Supreme Court is most likely to continue to find preemption: where there is an express statutory provision or regulation “with the force of law” or where the agency with expertise in the area has given real, deliberative consideration to the risk of which the plaintiff complains. Companies in highly federally regulated areas may find it appropriate to consider how to best position themselves to take shelter in this remaining area of implied preemption by, for example, seeking agency review and comment on specific decisions. Litigators are well advised to study the distinctions between *Wyeth* and *Geier* in determining how to best frame their case for implied preemption. In *Geier*, the defendant was able to identify specific competing objectives (promoting consumer acceptance of airbags via gradual introduction and encouraging innovation in the development of alternative supplemental restraint systems) that would have been frustrated by the plaintiffs’ proposed state law requirement of universal airbags. By contrast, in *Wyeth*, no such specific competing objectives disfavoring the expanded warning seem to have caught the Court’s attention.

Finally, *Wyeth* may have been a stitch in time. Had the decision come out in favor of preemption, Congressional action overruling the result might have been forthcoming. That Congressional action might have extended much further (abrogating the preemption clause in the Medical Device Amendments, for example) than the relatively narrow Supreme Court decision.

Please feel free to contact us with any questions.

Maura Kathleen Monaghan
+1 212 909 7459
mkmonaghan@debevoise.com

Roger E. Podesta
+1 212 909 6213
repodesta@debevoise.com

Mark P. Goodman
+1 212 909 7253
mpgoodman@debevoise.com

Anne E. Cohen
+1 212 909 6078
aecohen@debevoise.com

Mary Beth Hogan
+1 212 909 6996
mbhogan@debevoise.com