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**LIFE SCIENCES AND
PRODUCT LIABILITY UPDATE**

Wyeth v. Levine: "Tragic Facts Make Bad Law"

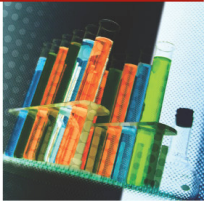
So says the dissent, in its lengthy opinion objecting to the decision by the Supreme Court of the United States in *Wyeth v. Levine*, No. 06-1249, slip. op. (U.S. Sup. Ct. March 4, 2009). In a 6-3 ruling against Wyeth, the Court held that the Food & Drug Administration's (FDA) approval of a drug warning does not protect a drug manufacturer, based on preemption, from state court failure-to-warn claims. State court juries, not the FDA, therefore, will provide the final word as to the adequacy of a drug label.

The "tragic facts" begin with Wyeth's drug Phenergan, which can cause irreversible gangrene if it enters a patient's artery during administration. This happened to Vermont violinist Diane Levine, who received a Phenergan injection for a migraine and nausea by the "IV-push" method. The Phenergan found its way into Levine's artery and she subsequently required amputation of her arm. At the time of Levine's treatment, Phenergan's labeling clearly warned of this precise danger, but the jury agreed with Levine that Wyeth's label should have instructed clinicians to use the IV-drip method rather than the higher risk IV-push method to administer the Phenergan. Wyeth appealed, and the Vermont Supreme Court upheld the trial court's denial of Wyeth's pre-trial motions and the jury verdict. The U.S. Supreme Court granted Wyeth's petition for writ of certiorari and reviewed the case.

The U.S. Supreme Court sided with the trial court in rejecting the two separate preemption arguments asserted by Wyeth: that it would have been impossible for Wyeth to comply with the state-law duty to modify Phenergan's labeling without violating federal law, and that recognition of Levine's state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA.

According to the Court, Wyeth could have added to or strengthened the Phenergan label without prior FDA approval and without violating federal law through the "Changes Being Effected" supplement process (CBE). Additionally, according to the *Levine* ruling, Wyeth's interpretation of Congress' "purposes and objectives" was incorrect. State court suits are not contrary to Congress' purposes and objectives because those suits "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."

The dissent sharply criticized the holding as wrongly focusing on the narrow issue of whether Wyeth had a duty to provide "an adequate warning about using the IV-push method" to administer Phenergan, instead of the real question: whether it is the FDA or a state court jury that has the authority and responsibility for determining the "adequacy" of Phenergan's warning. Drug labeling, according to the dissent, is "[t]he centerpiece of risk management" because it communicates to health care practitioners the FDA's "formal, authoritative conclusions" about how a drug can be used safely



and effectively. The dissent found no authority in the Food Drug & Cosmetic Act (FDCA) or its implementing regulations that would allow tort juries to second-guess or overrule the FDA's labeling decisions. In the dissent's view, allowing a jury to perform this function after a labeling decision has been made by the FDA causes a federal-state conflict and a frustration of the FDA's objectives, thus requiring preemption. The problem was described by the dissenting justices as one of focus; juries see only the product's risk in the vacuum of a particular plaintiff's case, whereas the FDA sees the overall benefits to all drug consumers of the product and its labeling. Thus, tort juries are ill-equipped to perform the FDA's cost-benefit balancing function.

IMMEDIATE IMPACT OF *LEVINE* RULING

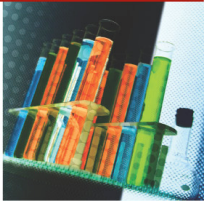
The impact of the *Levine* opinion is being widely and immediately felt as the Supreme Court has refused to hear appeals in two preemption cases. In 2008, the Third Circuit in *Colacicco v. Apotex* held that federal law guidelines preempted state-law claims that an antidepressant drug label did not sufficiently warn of the risks of suicide. In *Pennsylvania Employees Benefit Trust Fund v. Zeneca*, the same court found that state false advertising claims were preempted by federal law because the FDA has exclusive authority to regulate prescription drug advertisements. The Supreme Court has vacated the Third Circuit opinions and has remanded the cases for further consideration in light of *Levine*.

The *Levine* ruling paves the way for juries nationwide to “contradict and disregard the FDA's expert determinations.” *Levine* flatly rejected the FDA's position that not only must it be able to set consistent standards, but also that its labeling requirements are not merely a minimum safety standard, but the result of a responsible balance between benefits and risks.

FUTURE IMPACT OF *LEVINE* RULING

The victory for medical device manufacturers in *Riegel v. Medtronic* now seems fleeting, or at the very least, undermined by *Levine*. *Riegel's* ruling—making clear that state court juries may not second-guess the FDA's determination as to the safety of a Class III medical device that underwent the more stringent premarket approval process—reflected a wise approach to the determination of safety and effectiveness. The *Levine* holding will fuel the push to reverse the impact of *Riegel* that began with the introduction in both the House and the Senate of the Medical Device Safety Act of 2008 (H.R. 6381) (S. 3398) by members of Congress, including then-Senator Obama. Although the bills died with the conclusion of the 110th Congress, the current Congress and President Obama plan to support the continuation of this effort. A new bill just introduced in Congress, the Medical Device Safety Act of 2009 (H.R. 1346), similarly seeks to add language to the Medical Device Amendments of 1976. This language would specifically authorize state-law claims and defeat preemption. If passed, the law would gut *Riegel*, allowing state-law failure-to-warn claims related to medical devices.

The *Levine* decision also creates future confusion for drug manufacturers regarding the management of their drug labeling process. *Levine's* ruling appears to be at odds with the FDA's



recent clarification of the CBE supplement regulations. According to the FDA, it has long been its position that manufacturers are authorized to make CBE labeling changes to add or strengthen a contraindication, warning, precaution or adverse reaction only in limited circumstances: to reflect newly acquired information that is not merely cumulative of evidence already considered by the FDA, and where there exists a causal connection between the newly acquired information and the drug. Such limited circumstances were not present in the *Levine* case in which ample evidence showed that throughout the years, the FDA specifically and repeatedly considered the strength of Phenergan’s IV-push related warnings in light of new scientific and medical data. With this consideration and knowledge, the FDA deemed the Phenergan label in effect at the time of Levine’s incident as an appropriate warning about the risks of IV-push during Phenergan administration. The *Levine* opinion suggests to manufacturers trying to govern their future conduct that, contrary to the FDA’s clarification on CBE regulations, even if the FDA has previously considered certain contraindications, warnings or adverse reactions and has required no labeling changes, the manufacturer should nonetheless make CBE changes to its labeling.

The impact of *Levine* on the drug manufacturing industry likely will be to thwart efforts by manufacturers, particularly smaller companies, to pursue the development of innovative drugs. *Levine* endorses unregulated liability against drug companies. The cost, ultimately, will be placed on the individual consumer, who will have to pay higher prices for drugs to cover the price of potential jury verdicts finding liability for failure to warn.

FOR MORE INFORMATION

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