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Client Alert

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Supreme Court Rules State Law Tort Claims Involving Drug Labels Approved by FDA Are Not Preempted

In a major defeat for the pharmaceutical industry, the Supreme Court last week held by a 6-3 vote that federal drug labeling law does not preempt "failure to warn" claims filed in state courts. The case was one of the most widely anticipated business cases before the Supreme Court this year because it involved a central legal theme of the final years of the Bush administration--that federal legal and regulatory requirements should preempt conflicting state tort law claims.

The case, *Wyeth v. Levine*, upheld a $ 6.7 million Vermont jury verdict for musician Diana Levine, who lost most of her forearm to gangrene when Wyeth's anti-nausea drug Phenergan was improperly administered by a third party despite warning labels that were approved by the U.S. Food and Drug Administration (FDA). Levine brought state law tort claims alleging that Wyeth failed to provide an adequate warning about the significant risks associated with administering the drug by the IV-push method, whereby the drug is injected directly into a patient's vein. Phenergan is corrosive and causes irreversible gangrene if it enters a patient's artery and that risk increases when the drug is administered by the IV Push method instead of the IV-drip method, whereby the drug is introduced into a saline solution in an IV bag and descends slowly through a catheter inserted in a patient's vein. The Vermont jury determined that Levine's amputation would not have occurred if the drug label had included an adequate warning about the risks associated with the IV Push method of administration.

In *Wyeth*, the drug manufacturer had argued that it would have been impossible for it to comply with a state law duty to add a stronger warning against IV Push administration without violating the requirements governing drug approvals under the Federal Food, Drug, and Cosmetic Act (FDCA). The Court rejected that argument by reasoning that although, as a general rule under the FDCA, a drug manufacturer may change a drug label only after the FDA approves a supplemental application, the FDA's "Changes Being Effected" (CBE) regulation permits certain preapproval label changes that add or strengthen a warning to improve drug safety.

Pursuant to the CBE regulation, the Court noted that Wyeth could have unilaterally added a stronger warning about IV push administration and commented that there was no evidence that FDA would ultimately have rejected such a labeling change. This section of the majority opinion relied on two facts established by the trial: (1) that a more robust warning would have made a difference in whether the drug would have been administered by the IV Push method and (2) that this was only a failure to warn and not a duty to

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contraindicate case. The Court's decision also makes clear that the Court disapproved of Wyeth's view that the manufacturer's decisions concerning the content of a drug label is secondary to the FDA's oversight and the agency's ultimate decision-making on the appropriate label content. The Court underscored that it is a central premise of the FDCA and FDA's implementing regulations that the manufacturer bears responsibility for the content of the drug label at all times. As such, "[i]t is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Slip op. at 14.

The Court also rejected Wyeth's argument that requiring it to comply with a state law duty to warn by providing a stronger warning on the drug label would interfere with Congress' intent to have FDA serve as the expert agency concerning drug labeling decisions. In essence, Wyeth's position was that once the FDA had 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 had considered the stronger warning at issue. The Court held that argument was without merit because it was based on an improper interpretation of congressional intent and an overbroad view of the FDA's power to preempt state law. This part of the Court's opinion relies heavily on the Court's determination that the history of the FDCA shows that Congress did not intend to preempt state law failure to warn claims. Indeed the Court noted that if Congress had thought state lawsuits posed an obstacle to the objectives of the FDCA, it surely would have enacted an express preemption provision at some point during the FDCA's 70 year history.

Those of you who have followed this case know that Wyeth, in making the preemption argument, relied heavily on a prior FDA opinion in a preamble to a 2006 FDA regulation governing the content and format of prescription drug labels. The preamble declared that state law failure to warn claims interfered with the agency's statutorily prescribed role to approve drug labels. The Court refused to give the FDA preamble argument any deference. The Court noted, where, as here, Congress has not authorized FDA to preempt state law directly and where there is no specific agency regulation bearing the force of law that invokes preemption of state law claims, the agency's views expressed in the preamble alone are not persuasive. Indeed, the Court referenced the longstanding coexistence of state and federal law and the FDA's traditional recognition of state law remedies. In short, the Court concluded that Wyeth failed to persuade that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.

The *Wyeth* opinion does not affect the 2008 ruling by the Supreme Court in *Riegel v. Medtronic* that the Medical Device Amendments of 1976 preempt state law tort claims against the manufacturers of Class III medical devices. This dichotomy exists because *Wyeth* concerned implied preemption, whereas *Riegel* involved express language incorporated in the FDCA by the Medical Device Amendments of 1976 that expressly protects medical device manufacturers from many injury suits over Class III devices approved by FDA. Recently, a bill has been introduced in Congress to overturn the Court's decision in *Riegel*, and the Court's decision in *Wyeth* may encourage those efforts.

Indeed, the clear signal from the opinion in *Wyeth* is that the Supreme Court when dealing with cases raising preemption claims, will be guided first by the expressed intent of Congress and second by the assumption that the historic police powers of the states are not to be superseded by a federal act unless that is the clear and manifest purpose of Congress. That precedent seemed to make the difference in *Wyeth*. Looking at congressional intent, the Court noted that there was no express preemption provision in the 1962 Drug Amendments similar to that enacted for the Medical Device Amendments in 1976. The Court also concluded

that by regulation drug manufacturers remain responsible for updating their labels and cited the CBE regulation as providing that a manufacturer can change 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 its supplement application with FDA; it need not wait for FDA approval.

It should be noted that the Court ruling in *Wyeth* was very fact-specific, and the decision should not be read as forever barring the idea of federal preemption. The majority opinion simply held that preemption does not apply in this case. Nevertheless, unless Congress amends the FDCA to add a specific preemption clause for drugs, it seems unlikely that lower courts will entertain future preemption arguments in cases involving drug labels. Moreover, it is difficult to envision a stronger case in favor of the drug manufacturer than the one presented in *Wyeth*. Ms. Levin lost her arm after a physician's assistant improperly injected Phenergan and the drug invaded an artery and caused gangrene, necessitating amputation of her hand and lower arm. The label on the drug clearly warned that extreme care should be used with the IV Push method and explained in detail what would happen if the drug was administered improperly. Despite evidence that the physician's assistant had not followed the drug label's instructions, the Vermont jury found the drug's warnings insufficient.

These facts underscore the fundamental policy issue that is at the heart of the preemption debate: Who should make the decisions that will determine whether the benefits of a drug outweigh its risks and how those risks should be communicated? Should it be the FDA, the federal agency established by Congress to be the "expert", or 12 people pulled randomly for a jury role who see before them only the people injured by the drug and do not have before them the people who need the drug to cure or treat them or the full evidence considered by the FDA in approving the drug and determining the appropriate content for the label? After last week's decision, it is clear that efforts to defend against state tort law claims based on a preemption argument are most likely to succeed when they are based on express language in a federal statute (or a properly promulgated federal regulation) that makes compliance with a contrary state requirement impossible. Otherwise, manufacturers will continue to face the risk of large jury verdicts even though they have successfully navigated the long and expensive process of getting their drugs approved by the FDA.

Dozens of cases involving failure to warn claims against various drug companies that had been stayed pending the *Wyeth* decision will now move forward. The decision may also spur manufacturers to revise labels on drugs to include more extensive warnings to reflect new information about possible side effects and other risks. Should this occur, it will place even more burdens on drug manufacturers and the FDA because such changes will need to be brought before the agency for review and decision. Then, too, when drug labels are changed, it places new further demands on health care professionals who must balance the benefits versus the risks associated with the drug in making appropriate medical judgments for their patients.