# The End of the Federal Pre-emption Defense?

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A highly anticipated United States Supreme Court decision may greatly reduce the opportunity for defense attorneys to successfully raise federal pre-emption arguments. In *Wyeth v. Levine*, --- U.S. ---, 2009 U.S. LEXIS 1774, a 6-3 majority decision upheld a state law failure-to-warn tort claim against the defendant drug manufacturer Wyeth. It affirmed a decision awarding a plaintiff damages after she was administered a drug through the IV-push method instead of the IV-drip method. This caused gangrene to develop in the musician's arm and necessitated its amputation.

At the heart of the *Wyeth* opinion is whether the FDA's approval pre-empts related state tort law claims. The Supreme Court held that the FDA's standards created a floor, and not a ceiling in the regulation of drugs. The majority concluded that allowing state law failure-to-warn claims does not defeat Congressional intent for the FDA. A saving clause stating that state laws are only invalidated by direct conflict and a recent change allowing label changes by manufacturers without prior FDA approval were cited to support its decision.

The majority opinion delivered by Justice Stevens assumes two important findings from the trial court, namely that: (1) an additional warning would have prevented administration via the riskier IV-push method; and, (2) the FDA regulations permit a drug manufacturer to first change a drug label on its own and then seek FDA permission after. This second finding defeats the defendant's impossibility argument.

"Bad facts make bad law," Justice Alito penned in opening his dissent. He later pointed out that this claim would have made an "ideal medical-malpractice case", rather than a manufacturer liability case. In contrast to the majority, the dissent opinion recognized that six related warnings specifically addressing the risk of amputation were already present on the drug label, and were all ignored by the physician's assistant—thus a seventh warning was unlikely to make a difference. Additionally, the dissent argues that a proposed changed label was submitted to the FDA. Justice Stevens asserts that the labels were not significantly different, but Justice Alito argues the proposed label had a stronger warning about gangrene—and which the FDA rejected.

The dissent also espoused the importance of FDA pre-emption in the area of drug regulation. It recognized that the FDA should be the final judge of the safety of a drug based upon its ability to perform a cost-benefit analysis. By allowing state tort claims, the safety question is left to juries which lack the FDA's beneficial experience and expertise. As defense attorneys know well from personal experience, juries are often biased because they only see injured plaintiffs and not the many, many more people helped by the same product.

The dissent opinion by Justice Alito also uses *Geier v Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913 (2000), to support its position. In *Geier*, the U.S. Supreme Court found in favor of federal pre-emption against a negligent design state law tort claim. Pre-emption existed

because the Department of Transportation deemed a variety of passive restraint methods safe and a state decision that only side air bags were safe directly contradicted the DOT's policy decision.

The *Wyeth* dissent clearly expressed the belief that the result in *Wyeth* cannot be reconciled with *Grier* because the FDA told Wyeth its drug was safe but a Vermont jury said it was not. Justice Alito thusly concludes, "The state-law rule at issue here is squarely pre-empted. Therefore, I would reverse the judgment of the Supreme Court of Vermont."

Justice Stevens' majority opinion attempted to distinguish from *Geier* because, "[i]n short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling." In this way the majority does not completely close the door to all federal pre-emption defenses, acknowledging that "[a]lthough we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case."

The decision in *Wyeth* is very important because it is likely to apply to all pre-emption defenses. Most troubling, the majority in *Wyeth* failed to establish a useful standard for determining when a state tort law claim frustrates Congressional intent. Along with the inherent difficulties of interpreting Congressional intent, lower courts are left with no useful guidance as to when state law tort claims may be pre-empted by federal agency action. This will probably result in a case-by-case analysis similar to the 'evolving standards of decency' criterion.

The problems *Wyeth* may cause for defense attorneys are manifold. First, it is very difficult for defense attorneys to be certain when they can rely on pre-emption as a defense. Second, plaintiffs will likely claim that the applicable federal regulation, whatever it may be, is merely a floor that state tort law can surpass without conflicting Congressional intent. While this is not a novel argument for plaintiffs, *Wyeth* will certainly bolster its strength.

Additionally, the number of product liability claims brought against manufacturers may greatly expand. Whereas a federal agency standard is uniform making it easier to establish a precedent, state tort law liability may expose a business to different outcomes. This could greatly increase the cost of doing business, as companies will potentially be chasing 50 different standards of care.

Although *Wyeth* may not have sounded the death-knell for the federal pre-emption defense, it has clearly cast a severe blow. The effects of this blow will soon play out in court rooms across the nation. Therefore every defense attorney should be familiar with this case and its potential arguments that clever plaintiff's counsel will be sure to make based on this case.