



COMMENTARY

McGarity: Court takes up pre-emption doctrine

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The day before Americans went to the polls to choose a new president and Congress, the Supreme Court took up one of the most significant cases of its term. As part of its broad initiative to limit lawsuits against product manufacturers, the Bush administration has aggressively asserted the power of federal regulatory agencies to pre-empt lawsuits brought under state law. Most courts have disagreed, but the Supreme Court will soon have the final word. Although obscured by the election coverage, the case is highly significant for consumers of prescription drugs.

The specific case involves a lawsuit brought by Diana Levine, a professional guitarist from Vermont. Eight years ago, she went to a clinic complaining of a migraine. She received an injection of an anti-nausea drug called Phenergan.

The label on the drug, manufactured by Wyeth, cautioned that the method for administering the drug — the so-called "Push IV" method of direct injection into a vein — was risky because of the danger that the drug would be injected into an artery instead of a vein. But the label did not instruct doctors not to use the direct injection technique.

Unfortunately, the method made all the difference. The drug apparently missed the vein, reached an artery, and began killing tissue in her arm — a hazard known to the manufacturer when the medicine is introduced by direct injection, rather than the safer approach of an intravenous drip. In Levine's case, the inadequate labeling resulted in the amputation of her arm.

Litigation ensued. In court, Levine's lawyers argued that the label should either have either "counterindicated" direct injection or included a stronger warning against that dangerous technique. The jury agreed and awarded \$7.4 million in damages.

The question before the Supreme Court deals with an abstract legal rule called the pre-emption doctrine. The Constitution says that a state law that

conflicts with federal law is null and void. Wyeth argues that because its label was approved by the U.S. Food and Drug Administration, Vermont's more protective common law is pre-empted.

Wyeth maintains that the common law duty to warn conflicts with the company's obligation to use FDA-approved labels. Since the Phenergan label specifically allows doctors to use the direct injection technique and cautions against injecting into arteries, the company maintains, complying with a common law duty to tell doctors to avoid that technique or provide a more powerful warning would violate the federal law or at least pose an obstacle to FDA's implementation of federal drug labeling policy. Levine's lawsuit is therefore pre-empted by federal law, Wyeth argues.

Levine's lawyers see no such conflict between FDA's requirements and Vermont's laws. FDA regulations permit manufacturers to change the label at any time to contraindicate a previously permitted use or to contain a more stringent warning. And though FDA has the power to disapprove a company's label change, it has never done so.

Wyeth's obligation to comply with the federally approved label came up at trial. The common law rules allowed the company to argue that FDA approval demonstrated that the label was not defective. But the jury was unconvinced and ruled for Levine.

If allowed to stand, Levine's suit will encourage Wyeth and other drug companies to change their labels when they obtain new data or reanalyses of existing data showing that a drug presents greater risks than the company anticipated when it sought FDA approval.

More importantly, the common law is ordinarily the only vehicle for ensuring that injured victims can be compensated for harm caused by defective products. Federal regulations are designed to protect the public, not compensate victims.

If regulatory agencies were perfect, common law liability might be unnecessary. But by all accounts, FDA and other federal agencies are starved for resources and often more concerned with meeting industry demands for expeditious approvals than with protecting the public.

Of course, pharmaceutical litigation is hardly the only area in which pre-emption would shield manufacturers from liability for dangerously defective products. A broad victory for Wyeth will make it harder to hold manufacturers of other products to account, too, including manufacturers of defective toys, poorly designed automobiles and flammable clothing.

The court's eventual ruling, which should come early next year, could shape the law for years to come.

McGarity is a member scholar of the Center for Progressive Reform and the author of 'The Preemption War: When Federal Bureaucracies Trump Local Juries.'

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