

THE PREEMPTION WAR

A victory for consumers

■ Ruling against drug company a win in battle for patient safety

By THOMAS O. MCGARITY

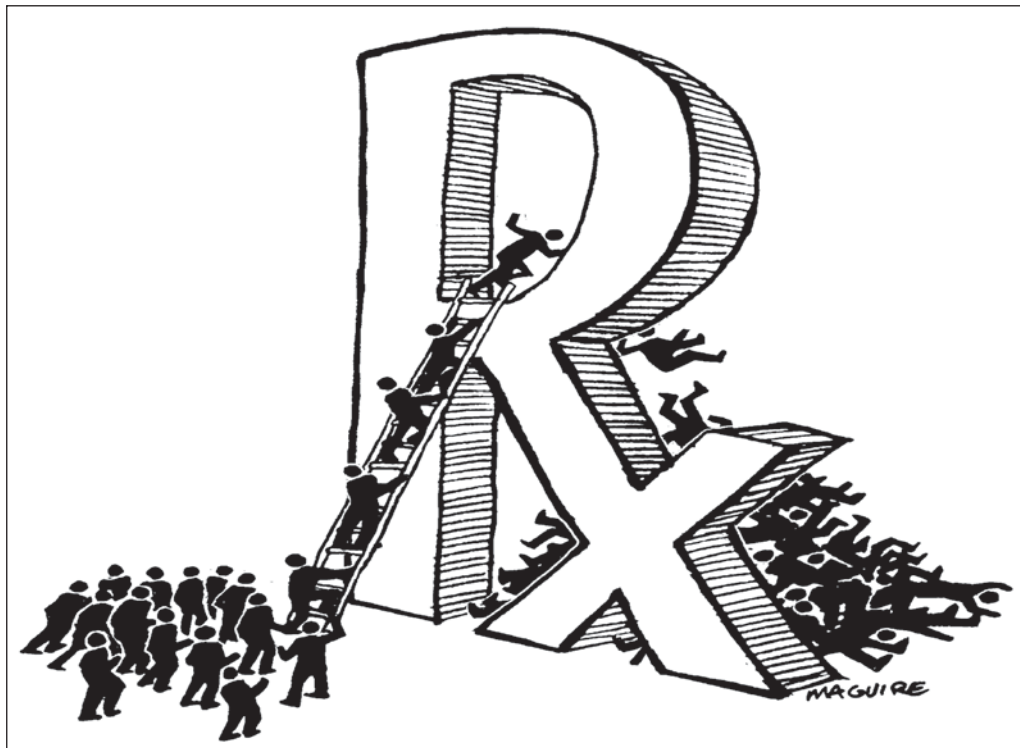
THE Supreme Court last week ended an acrimonious battle between large pharmaceutical companies and patients injured by inadequately labeled prescription drugs. The court in *Wyeth v. Levine* ruled that a Vermont jury could hold one of the world's largest drug companies accountable for the expense and pain that a professional guitarist and pianist suffered when its anti-nausea drug caused her to lose her right hand.

The court's 6-3 holding marks a surprisingly solid victory for patients on an issue that has occupied state and federal courts since the early days of the George W. Bush administration — whether federal regulation of prescription drugs “pre-empts” lawsuits in state courts over drug safety.

The opinion is also a rare win for consumers in the broader “pre-emption war” that has been raging in Congress and the courts over whether federal regulatory agencies should trump local juries.

The war continues in other areas where federal agencies regulate potentially dangerous products, set standards for airline, railroad and motor carrier safety, and attempt to protect consumers from unscrupulous banks and credit reporting agencies. But the Supreme Court's well-reasoned opinion should make federal bureaucracies think twice before concluding that they are the only game in town.

The jury in *Wyeth v. Levine* found that the drug's label did not adequately warn the physician's assistant who administered it about the dangers posed by the technique she used to inject it. The label mentioned that the technique could cause a severe reaction if the drug entered an artery



instead of a vein, but the jury found that the warning was inadequate and that the assistant would have used a far less dangerous alternative technique if adequately warned.

Wyeth pointed out that the Food and Drug Administration had over the years approved the drug's label and several modifications, but the jury was not persuaded that FDA approval alone ensured that the label's warning was adequate. Indeed, the evidence demonstrated that in the years following FDA approval, many similar amputations had resulted, and yet Wyeth had not submitted a clearer or more dramatic warning for FDA approval. For its part, FDA lacked authority to require Wyeth to change its label even in light of this clear indication that the existing label was not working.

On appeal, Wyeth pulled out its ace in the hole, asserting that the jury's finding was irrelevant because the FDA's approval of the label pre-empted any claim by any plaintiff that it was inadequate.

The U.S. Constitution provides that federal law is the “supreme law of the land.” State laws therefore must

yield to federal laws when they conflict. In deciding whether such conflicts exist, a court must ascertain the intent of Congress in enacting the law that empowers the federal agency to act.

In this case, the relevant federal statute did not explicitly address the question of pre-emption, so Wyeth argued that the pre-emption was implied because it was impossible for the company to comply with both its duty to use the federally approved label and the asserted common law duty to use a more stringent warning.

The Supreme Court brushed the argument aside, noting that, under FDA regulations, the company was free to add a more stringent warning unilaterally, and making clear that if Congress wanted the federal statute to preempt state tort laws, it could easily have said so on one of the many occasions that it had revisited the statute.

The court also rejected Wyeth's argument that allowing juries to entertain such claims would hamper the broader objectives of the federal statute. Indeed, it noted that the FDA had always welcomed state common law actions right up until it suddenly changed its position in

2006.

Throughout its opinion, the court stressed that the “manufacturer bears responsibility for the content of its label at all times.” In our civil justice system, innocent people generally have recourse to state courts to hold companies accountable when they shirk their legal responsibilities. The court wisely prevented Wyeth from palming off its responsibility to warn doctors and patients onto an overworked and underfunded federal agency that had been more concerned with meeting industry demands for rapid new drug approvals than with protecting patients from dangerous drugs.

Federal agencies and state courts have complementary roles to play in protecting consumers from dangerous products and activities. The decision in this case is a welcome sign that the Supreme Court will allow both of them to remain on the stage.

McGarity is a professor of law at The University of Texas at Austin, a member scholar of the Center for Progressive Reform, and the author of “The Pre-emption War: When Federal Bureaucracies Trump Local Juries,” (Yale Univ. Press 2008).