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Thomas McGarity: A rare win for consumers

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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 vs. Levine* ruled that a Vermont jury could hold a major drug manufacturer accountable when its anti-nausea drug caused a professional musician to lose her right hand.

The holding is a rare win for consumers in the broader "preemption 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 vs. 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.

Wyeth pointed out that the Food and Drug Administration had approved the drug's label, but the jury was not persuaded that FDA approval alone ensured the adequacy of the warning. 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. It argued FDA's approval of the label preempted any claim by any plaintiff that it was inadequate.

The U.S. Constitution provides that state laws 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 mention preemption, so Wyeth argued that preemption 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 this argument aside, noting that, under FDA regulations, the company was free to add a more stringent warning unilaterally.

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 until it suddenly changed its position in 2006.

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 its responsibility off onto an overworked and underfunded federal agency that was more concerned with approving drugs than with protecting patients.

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.

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