

OPINION

DANGEROUS Devices

Consumers should be able to sue, keeping pace with 'Wyeth.'

BY SOL WEISS

On March 5, the U.S. Supreme Court, in *Wyeth v. Levine*, reaffirmed the valuable role consumer lawsuits serve in keeping Americans safe, by ruling that an individual can hold a drug manufacturer accountable when the company knows of a risk associated with one of its products but does not convey it in a suitable warning. The clear message of the 6-3 decision in *Wyeth* was that a U.S. Food and Drug Administration (FDA)-approved label does not insulate drug manufacturers from responsibility to update warnings based on knowledge of risks acquired after initial approval of the warning. By so holding, the Supreme Court exposed the injustice of its ruling from the prior term in *Riegel v. Medtronic*, which prohibited consumer lawsuits against medical device manufacturers when users were injured.

In *Wyeth*, Justice Clarence Thomas stated that there must be a clear indication of congressional intent, as opposed to the inference of congressional or agency purpose, for state law to be pre-empted under the supremacy clause. The Court held that the FDA's purported rulemaking could not immunize corporate misconduct by denying injured consumers access to the civil justice system.

The *Riegel* decision held that the FDA approval process pursuant to the Medical Device Act of 1976 warranted pre-emption of state court actions against manufacturers. While the Court's decision in *Riegel* can be supported by the intent expressed by Congress in the Medical Device Act, the effect of that decision on the rights of injured consumers cannot.

After *Wyeth*, consumers injured by dangerous prescription drugs may maintain state court actions to seek compensation for those injuries, while consumers injured by dangerous medical devices are precluded from doing so. Reviewing *Wyeth's* holdings

and reasoning demonstrates that Congress cannot permit this injustice to continue and must amend the Medical Device Act to protect consumers of medical devices.

The *Wyeth* court established a narrow framework for assessing a drug manufacturer's contention that federal drug laws and the FDA's approval of a drug's label pre-empt a state law failure-to-warn claim. The drug industry, as well as the FDA, had made broad claims of conflict pre-emption: specifically, that when the FDA approved a drug label, the agency had established both a "floor and a ceiling for drug regulation."

The Court rejected this position, stating that the "most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary" and that Congress did not regard state tort litigation "as an obstacle to achieving its purposes." The Court found that Congress and the FDA had long recognized that "[s]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation," as "[s]tate tort suits uncover unknown drug hazards" and "serve a distinct compensatory function." It concluded that a drug manufacturer's claim of implied conflict pre-emption will fail when it cannot present "clear evidence" that the FDA would "have prohibited [the manufacturer] from adding a stronger warning."

The decision reaffirmed two cornerstones of Supreme Court pre-emption jurisprudence: the "purpose of Congress" and the "presumption against preemption." In doing so, constitutional checks and balances were restored. Congressional intent undisputedly limited FDA oversight so that the FDA could not be the exclusive means of ensuring drug safety and effectiveness.

In light of the "historic presence of [these] State law" remedies, the Court found that the presumption against pre-emption applies when a drug manufacturer claims implied pre-emption based on federal drug law.

The court rejected *Wyeth's* claim that modifying its label without FDA approval would have rendered its drug misbranded under federal law and distribution of that drug unauthorized. The misbranding argument was premised on a "fundamental misunderstanding" of federal drug regulation: namely, that "the FDA, rather than the manufacturer, bears primary responsibility for drug labeling." The court squarely rejected that proposition, explaining that, through Congress' and the FDA's "many amendments" to the federal statute and implementing regulations, "it has remained a central premise of Federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."

The same reasoning should apply to medical devices. The anomaly of permitting consumers to pursue state court actions when injured by dangerous prescription drugs, but prohibiting consumers from proceeding against manufacturers when the injury arises from a medical device, cannot continue. The *Wyeth* decision and fundamental notions of fairness, justice and protection for consumers compels Congress to amend the Medical Device Act, permitting consumers to bring state court actions when injured by medical devices.

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