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Plaintiffs Attorneys Elated After *Wyeth* Ruling

Defense Lawyers Looking for Avenues to Continue Pre-emption Battle

By Gina Passarella And Tony Mauro

The city's plaintiffs lawyers were in a mood Wednesday to become the first mass of humanity to dance down Broad Street since the Phillies won the World Series.

Their cause for jubilation: the U.S. Supreme Court's much anticipated decision in [Wyeth v. Levine](#). In a 6-3 decision, the high court affirmed lower courts' rulings that state tort claims over the warning labels of pharmaceuticals could not be pre-empted by federal law simply because the U.S. Food and Drug Administration had approved the warning labels.



The opinion was being widely circulated among pharmaceutical defense attorneys as well.

Defense attorneys were a more somber crowd on Wednesday, finding great fault with the court's ruling and vowing that the fight is far from over.

The general consensus among the defense bar was that it was no surprise that the court didn't find for sweeping pre-emption of state claims, but they were hoping for some happy medium. One surprise was that Justice Clarence Thomas, in a separate concurring opinion, agreed with the outcome of the case.

Even if they had seen a loss coming, some defense attorneys said they would have expected a 5-4 split. Justice John Paul Stevens wrote the majority opinion and was joined by Justices Anthony Kennedy, David H. Souter, Ruth Bader Ginsburg and Stephen G. Breyer. Breyer also filed a concurring opinion, and Thomas concurred in the result.

The court's ruling has plaintiffs attorneys gearing up for more cases in state court.

Fredric Eisenberg of plaintiffs firm Eisenberg Rothweiler Winkler Eisenberg & Jeck said the court's ruling was "profoundly significant" for any consumer of prescription medication.

"This case involved a concerted effort by the Bush administration, working in tandem with the pharmaceutical industry, to close courthouse doors to consumers seriously injured by defective pharmaceuticals," Eisenberg said Wednesday. "Today's 6-3 decision by the Supreme Court is an unqualified rejection of that effort. As such, juries will again be asked in courtrooms around this country, and shortly here in Philadelphia, to hold pharmaceutical companies accountable."

The case was labeled by many watchers as one of the most significant business cases to go before the court this term, he said. The ruling shows that consumers, and not businesses, prevailed, Eisenberg said.

Raymond Williams focuses his pharmaceutical defense practice out of the Philadelphia office of DLA Piper. He said his initial reaction was that the ruling is wrong, but the defense bar has to live with it. That doesn't mean he doesn't see a light at the end of the tunnel.

"I think it's obviously difficult for pharmaceutical companies to deal with state tort claims in different jurisdictions which will say different things about the labeling, about the product, about the adverse events," Williams said. "I think it's unfair to ask a jury of 12 people to decide whether a label adequately reflects the knowledge of the science and the medicine at the time the label was issued."

Williams said he hopes there will be another case that gives the courts a chance to rule that these types of cases raise federal questions and therefore should only be heard in federal court.

While he wasn't necessarily pleased with the decision, Williams said he wasn't surprised. He said he figured there was a 50-50 chance of it going the pharmaceutical companies' way. He said he was a bit surprised that Thomas was in the majority and thought the case would have gone 5-4.

Fred T. Magaziner, a mass torts partner in Dechert's Philadelphia office, said this ruling is very disappointing for pharmaceutical companies.

"It does not adequately take into account the tension that they have to deal with on a day-by-day basis between their obligations to the FDA and the standards that are applied to them by juries who are called upon to decide individual cases," he said.

Magaziner said Justice Samuel A. Alito Jr. got it right in his dissent when he said a jury only has an injured person in front of it and can't take the longer view taken by the FDA in weighing the benefits of a drug when determining the appropriate warning label. Alito was joined by Chief Justice John G. Roberts Jr. and Justice Antonin Scalia.

Despite what's being seen as a big loss for the pharmaceutical field, Magaziner said, the court's ruling isn't the last to be heard on this issue. The *Wyeth* case, he said, left undecided several pre-emption issues and only ruled on the "failure to warn" issue. He said it will be "fascinating" to see how those other tangential pre-emption issues are handled in future cases. Magaziner also said *Wyeth* was very fact-specific and a similar case with a different fact pattern may be decided in a different way.

Sol Weiss, of plaintiffs firm Anapol Scwhartz Weiss Cohan Feldman & Smalley, attended oral arguments in *Wyeth* . He said it seemed clear to him that the majority of justices were against pre-emption. Weiss said that, at least as far as Thomas writes in his concurring opinion, the pre-emption issue raised in *Wyeth* is a settled one. Weiss did say, however, that there can be some wiggle room under the opinion in which federal law would trump state claims.

But as a general matter, Weiss said, the ruling takes away the "knee-jerk" claim of pre-emption that seemed to be filed in every case.

Weiss had a similar pre-emption case involving the anti-depressant Zoloft that went up to the 3rd U.S. Circuit Court of Appeals and was consolidated with another case involving Paxil. The 3rd Circuit ruled against the plaintiffs in the case, *Colacicco v. Apotex Inc.* , and Weiss and the other plaintiffs attorneys appealed to the U.S. Supreme Court in October. Weiss said the case is still pending there and, while he hopes the *Wyeth* ruling will make it a moot point, he isn't sure.

In *Wyeth* , the court ruled that the federal drug labeling law did not pre-empt the state court claim of Vermont musician Diana Levine, who sued when she lost her forearm in 2000 to gangrene because of improper administration of Phenergan. The labeling on the Wyeth-produced anti-nausea drug, she claimed, had failed to adequately warn medical personnel that the method used to give her the drug, an "IV-push," was dangerous and could lead to gangrene.

"Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling," Stevens said. Stevens also noted that until recent years, the Food and Drug Administration viewed state litigation as complementary to its regulations.

The decision means Levine will finally benefit from a roughly \$7 million jury award she won in 2004, plus interest, which Wyeth had challenged on federal pre-emption grounds. (Earlier, Levine also reached a settlement with the Vermont clinic that administered the drug.)

Thomas offered a powerful concurrence to the liberal Stevens' majority, suggesting he'd go even further than Stevens in questioning federal pre-emption doctrine. Thomas said "congressional and agency musings" about possible intent to pre-empt state suits are not adequate substitutes for explicit pre-emption provisions enacted into law.

Alito acknowledged the force, at a human level, of plaintiff Levine's case against Wyeth. "This case illustrates that tragic facts make bad law." Alito said that under federal law, it is the job of

the FDA, not state juries, to make the safety determinations that go into deciding the appropriate labeling and warnings for a drug.

Bad for Clients, Good for Business?

Aside from the major legal implications a ruling either way in *Wyeth* could have had, there was a clear business undercurrent concerning both the plaintiffs and defense bars. A finding of sweeping pre-emption had the potential to cut out a lot of work for both sides by cutting out the numerous "failure to warn" battles waged in state court.

In an article in *The Legal* that looked at this issue a few months ago, one defense attorney said a ruling in favor of pre-emption would impact the workload of both sides.

"For the plaintiffs attorneys, a large chunk of their business goes bye-bye," he said. While not all of the cases would go away, he said, it would mean another hurdle for plaintiffs lawyers to jump and could force them to prove drug companies deceived the FDA during the approval process.

"From the defense side, obviously it's a huge win for companies," he said in November. "For defense lawyers, much like plaintiffs lawyers, we will have to retool from a litigation standpoint because there won't be nearly as many pharma cases."

But despite a concern that at least some of the work might have gone away at least for some of the cases, most attorneys, both back in November and this week, said a ruling in favor of pre-emption could very likely have been overturned by legislation passed by a Democratic-controlled Congress and approved by the Obama administration.

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